California Department of Health Services

Pandemic Influenza Preparedness and Response Plan

September 8, 2006

California Department of Health Services

An annex to the CDHS Public Health Emergency Response Plan and Procedures

Pandemic Influenza Preparedness and Response Plan

California Department of Health Services

Table of Contents

List of Tables

List of Figures

List of Appendices

Chapter 1.

OVERVIEW OF THE PANDEMIC EMERGENCY PREPAREDNESS AND RESPONSE PLAN

PURPOSES OF THE PLAN

The California Department of Health Services (CDHS) Pandemic Influenza Preparedness and Response Plan:

- Outlines key assumptions for statewide pandemic planning and response;
- summarizes the legal and statutory authorities regarding public health;
- Explains the CDHS emergency management organization;
- defines the CDHS concept of operations for pandemic influenza response; and
- Lists actions CDHS will undertake in preparing and responding to an influenza pandemic.

The plan outlines the roles and strategies of CDHS in coordinating the public health response to a pandemic with local health departments, the healthcare community, the federal government, and other key partners.

Consistent with CDHS' mission "to protect and improve the health of all Californians," this plan provides a framework for CDHS pandemic influenza preparedness, response, and recovery activities. The goal of these activities is to reduce the morbidity, mortality, and social and economic disruption caused by pandemic influenza. The plan is an annex to the CDHS *Public Health Emergency Response Plan and Procedures* and is consistent with the U.S. Department of Health and Human Services Pandemic Influenza Plan, November 2005.

CDHS will carry out the response activities described in this plan in collaboration with the Emergency Medical Services Authority (EMSA), the California Health and Human Services Agency, the Governor's Office of Emergency Services, Governor's Office of Homeland Security other state agencies, local health departments, and tribal entities.

Chapters and appendices provide a framework for CDHS' preparedness activities and describe essential functions for conducting surveillance, case investigation, and treatment; preventing spread of the disease in the community; maintaining essential services; and other actions before, during, and after a pandemic.

MAINTENANCE OF THE PLAN

The CDHS *Pandemic Influenza Preparedness and Response Plan* is a dynamic document and will be updated periodically to reflect new developments in understanding of the novel influenza virus with potential to cause a pandemic, its transmission, prevention, and treatment. It will be exercised to identify operating challenges and promote effective implementation. Plan updates will also incorporate changes in response roles and improvements in response capability developed through ongoing planning efforts.

LIST OF ABBREVIATIONS

Abbreviation	Definition
CAHAN	California Health Alert Network
Cal/OSHA	California Occupational Safety and Health Administration
CDC	Centers for Disease Control and Prevention
CDFA	California Department of Food and Agriculture
CDHS	California Department of Health Services
DCDC	Division of Communicable Disease Control
EMS	Emergency Medical Services
EMSA	Emergency Medical Services Authority
Epi-X	Epidemic Information Exchange
EPO	Emergency Preparedness Office
EPSU	Emergency Pharmaceutical Services Unit
FDA	U.S. Food and Drug Administration
HEPA	High Efficiency Particulate Air Filter
HHS	U.S. Department of Health and Human Services
JEOC	Joint Emergency Operations Center
NIMS	National Incident Management System
PCR	Polymerase Chain Reaction
PIWG	Pandemic Influenza Work Group
SEMS	Standardized Emergency Management System
VAERS	Vaccine Adverse Event Reporting System
VRDL	Viral and Rickettsial Disease Laboratory
WHO	World Health Organization

INTRODUCTION

Pandemic Influenza Background

Influenza, also known as the flu, is a disease that attacks the respiratory tract (nose, throat, and lungs) in humans. Although mild cases may be similar to a viral "cold," influenza is typically much more severe, usually comes on suddenly, and may include fever, headache, tiredness (which may be extreme), dry cough, sore throat, nasal congestion, and body aches and more often results in complications such as pneumonia. Seasonal influenza is a yearly occurrence that kills primarily persons aged 65 and older and those with chronic health conditions and causes significant economic impact. Those who are exposed, but do not succumb, develop immunity to the strain circulating that year.

Worldwide pandemics of influenza occur when a novel virus emerges to which the population has little immunity. The 20th century saw three such pandemics, the most notable of which was the 1918 Spanish influenza pandemic that was responsible for 20 million deaths throughout the world.

Public health experts are now concerned about the risk of another pandemic arising from the current epidemic of avian influenza that is spread rapidly and has affected domestic and wild birds in Asia, Africa, and Europe. When strains of avian influenza interact with the common strains of human influenza, a mutation can occur, creating a virus capable of human-to-human transmission, initiating a pandemic. Depending on the pathogenicity of such a virus, between 25 to 35 percent of the population may become ill and nearly 200,000 Californians may die. This level of disease activity would disrupt all aspects of society and severely affect the economy.

The impact of a pandemic cannot be predicted precisely because it will depend on the virulence of the virus, how rapidly it spreads, the availability of vaccines and antiviral medications, and the effectiveness of pharmaceutical and non-pharmaceutical community containment measures.

World Health Organization Pandemic Phases

This plan rests on a conceptual framework of public health functions (preparedness and communication; surveillance and detection; and response and containment), coupled to WHO's pandemic phases described below.[1]

[1] In May 2006, WHO announced that it is reviewing and may revise the pandemic influenza phase definitions. For current definitions, see the WHO website at www.who.org.

INTERPANDEMIC PERIOD

WHO Phase 1. No new influenza virus subtypes have been detected in humans. An influenza virus subtype that has caused human infection or disease may or may not be present in animals. If present in animals, the risk of human infection or disease is considered to be low.

WHO Phase 2. No new influenza virus subtypes have been detected in humans. However, a circulating animal influenza virus subtype poses a substantial risk of human disease. The distinction between Phases 1 and 2 is based on the risk of human infection or disease resulting from circulating strains in animals, as assessed by various factors and their relative importance according to current scientific knowledge. Factors may include pathogenicity in animals and humans, occurrence in domesticated animals and livestock, (as opposed to only in wildlife), whether the virus is enzootic or epizootic, and whether the virus is geographically localized.

PANDEMIC ALERT PERIOD

WHO Phase 3. Humans have been infected with a novel virus subtype, but human-to-human spread has not occurred, or it has occurred in only rare instances of close contact.

Examples:

- One or more unlinked human cases with a clear history of exposure to an animal or other non-human source (with laboratory confirmation in a WHO-designated reference laboratory).

- Rare instances of spread from a case to close household or unprotected healthcare contacts without evidence of sustained human-to-human transmission.

- One or more small independent clusters of human cases (such as family members) who may have acquired infection from a common source or the environment, but for whom human-to-human transmission cannot be excluded.

- Persons whose source of exposure cannot be determined but who are not associated with clusters or outbreaks of human cases.

WHO Phase 4. Small cluster(s) of cases with limited human-to-human transmission are documented, but spread is highly localized, the virus is not well adapted to humans.

Examples:

- One or more clusters involving a small number of human cases, such as a cluster of less than 25 cases lasting less than two weeks.

- The appearance of a small number of human cases in one or more geographically linked areas without a clear history of a non-human source of exposure and for which the most likely explanation is considered to be human-to-human transmission.

WHO Phase 5. Larger cluster(s) appear, but human-to-human spread is still localized, suggesting that the virus is becoming increasingly better adapted to humans, but may not yet be highly transmissible. The risk of pandemic is now substantial.

Examples:

- Ongoing cluster-related transmission, but the total number of cases is not rapidly increasing, such as a cluster of 25 to 50 cases lasting from two to four weeks.

- Ongoing transmission, but cases appear to be localized (remote village, university, military base, island).

- In a community known to have a cluster, a small number of cases appear whose source of exposure is not readily apparent. The virus is beginning to spread more extensively.

- Clusters caused by the same or closely related virus strains appear in one or more geographic areas without rapidly increasing case numbers.

PANDEMIC PERIOD

WHO Phase 6. Increased and sustained transmission is documented in the general population.

POSTPANDEMIC PERIOD

Although not part of the WHO Phases for tracking the emergence of a pandemic, mitigation and recovery are essential for emergency planning and are incorporated as a part of this plan. Mitigation and recovery should focus on continuing public health actions, including communication with the public on issues such as when public gatherings can resume and continued monitoring of possible outbreaks of infection.

ASSUMPTIONS AND PLANNING PRINCIPLES

Key assumptions and limitations guiding CDHS pandemic influenza planning and response activities are listed below.

- A pandemic is a public health emergency that rapidly takes on substantial political, social, and economic dimensions. A broad range of private sector partners and government agencies, in addition to those dealing with public health, should be engaged in pandemic preparedness planning. A pandemic is likely to affect everyone in California: no amount of planning will allow "business as usual" in any sector of society or government.

- The course of pandemic influenza will be governed by factors that cannot be known in advance. Properties of the novel virus, including virulence, principal mode of transmission, timing and duration of viral shedding, and attack rate in different risk groups may differ from those of seasonal influenza strains.

- The first human cases of infection with a novel influenza virus will likely occur in outside of the U.S. and will be detected by the global surveillance network.

- An influenza pandemic could last from 18 months to several years, with two to three waves of activity.

- Activities identified in any given pandemic phase are not necessarily completed during that phase; activities started in one phase may continue into subsequent phases.

- Decisions about non-pharmaceutical community containment measures will be made in an atmosphere of considerable scientific uncertainty. Containment measures must be adapted to the epidemiologic context of each phase of the pandemic.

- Non-pharmaceutical community containment measures will be the principal means of disease control until adequate supplies of vaccine or antiviral medications are available.

- Vaccination and antiviral treatment are anticipated to be the most effective pharmaceutical strategies for reducing pandemic influenza morbidity and mortality. However, effective vaccines or antiviral medications may be delayed or in limited supply. CDHS will promote and coordinate the use of vaccines or antivirals based on their availability and the best scientific evidence at the time.

- CDHS, working with the Governor's Office of Emergency Services, will continually strive to assure adherence with the State's Standardized Emergency Management System (SEMS) and the National Incident Management System (NIMS).

- California's standard operating procedure is for all levels of governance to coordinate emergency response activities through SEMS.

- CDHS may take actions described in this plan or activate its emergency management organization without local or state proclamation of emergency.

- Depending on the situation, CDHS may activate all or portions of the plan.

- California's public health system is composed of local health departments with authority and responsibility for public health preparedness and response at the local level. CDHS leads, supports, and coordinates this effort and provides statewide policy guidance. CDHS provides cross-jurisdictional coordination during a multi-jurisdictional emergency and assistance if local resources are overwhelmed by the needs of the event. Although pandemic influenza may affect multiple jurisdictions simultaneously, all jurisdictional responsibilities are maintained. CDHS will provide additional support to leadership at the local level, without usurping the authority of local health departments.

- CDHS may modify and further define the federal guidance as necessary for allocating vaccines and antivirals to California's local health departments. CDHS Emergency Pharmaceutical Services Unit (EPSU) will be responsible for obtaining and distributing vaccines and antiviral drugs made available to California.

- The ability of the federal government to support California will be limited at the onset of a pandemic and may continue to be limited for an extended period. The State, local communities, and tribal entities will have to address the pharmaceutical and non-pharmaceutical community containment effects of a pandemic with available resources. Planning for continuity of governance at the state and local levels and continuity of operations (for the private sector) is an essential component of pandemic influenza preparedness.

- Communication is a critical aspect of all emergency planning and response. All programs involved in planning for and responding to pandemic influenza and other public health emergencies must ensure timeliness and accuracy of communication, including risk communications.

- CDHS will activate its risk communication strategies and quickly disseminate public advisories and alerts based on information from the Centers for Disease Control and Prevention (CDC) and other credible sources.

- Numerous people cross the California-Baja California border daily. Coordination with representatives from Baja California on pandemic influenza activities is essential for an effective response.

- CDHS and local health departments will work with tribal entities, Indian Health Clinics, the federal Indian Health Services, and other organizations to assure coordination.

- Special populations will be assessed and included within the planning, response, mitigation, and recovery process.

AUTHORITIES

- **California Emergency Service Act (Government Code Title 2, Division, Chapter 7, Section 8550 *et seq.*)**: Confers emergency powers upon the Governor and chief executives of political subdivisions of the state to provide for state assistance in organization and maintenance of emergency programs; establishes the Governor's Office of Emergency Services; assigns functions to state agencies to be performed during an emergency and provides for coordination and direction of emergency actions of those agencies; and establishes mutual aid procedures. Authority for the creation of standby orders exists in Government Code section 8567. Authority to suspend statutes and agency rules exists in Government Code section 8671.

- **California Health and Safety Code Sections Pertaining to State Authorities:**
    - **Sections 100170-100180**: Establishes the authority of CDHS to enforce regulations to address threats to the public health.

    - **Sections 120125-120140:** Establishes the authority of CDHS to investigate and control communicable disease within the state.

    - **Sections 120145-120150:** Establishes the authority of CDHS to take actions related to persons, animals, or property to control threats to public health, including quarantine, isolation, inspection, disinfection, and destruction of property.

- **California Health and Safety Code Sections Pertaining to Local Authorities**:
    - **Sections 101000, 101025, 101030:** Establishes the authority of county health officers to preserve and protect the public health by enforcing county orders, ordinances, and statutes pertaining to public health.

    - **Sections 101375, 101400, 101405, 101415, 101450, 101460, and 101470:** Establishes authority of cities to consent or contract with the county to provide performance of public health functions and statute enforcement. In the absence of consents or contracts with the county, authorizes cities to appoint a health

officer to enforce and observe all orders, ordinances, quarantines, regulations, and statues relating to public health.

- **Sections 101040, 101475:** Authorizes county and city health officers to take preventive measures during emergency.

- **Section 120175:** Authorizes the local health officer to take measures necessary to control the spread of communicable diseases.

- **California Food and Agriculture Code 9562**: Establishes provisions for the state veterinarian to quarantine animals or animal products and to take appropriate disease control action to control or eliminate diseases from animal populations.

- **California Government Code 8549.10 and 8549.11**: Establishes the Emergency Response Team for State Operations of eight specific Directors including the CDHS Director, and allows CDHS to enhance the continuity of government during major events, such as a pandemic influenza outbreak.

- **Executive Order No. W-9-91:** Mandates that each state agency and department (e.g., CDHS) is responsible to prepare for and respond to emergencies. It mandates emergency preparedness and response assignments for all state agencies and departments under the coordination of OES.
- **Executive Order No. S-04-06**: Directs state agency and department heads to meet on a regular basis to establish common strategies and actions for continued and enhanced emergency preparedness, response, recovery and mitigation efforts.
- **Administrative Order No. 79-22**: Details the emergency preparedness and response functions of each department (e.g., CDHS). This Administrative Order guides OES and all departments in coordinating priority tasks and programs related to emergency preparedness, response, and recovery in accordance with the OES *State Emergency Plan.*

REFERENCES

- **California Department of Health Services, Public Health Emergency Response Plan and Procedures, November 2005.**

- **Emergency Medical Services Authority, Disaster Medical Response Plan, July 1992.**

- **Memorandum of Understanding, Department of Health Services and Emergency Medical Services Authority, July 1988**: Details the relationship between CDHS and EMSA in planning for and responding to a catastrophic disaster and describes the specific responsibilities of each department.

- **Governor's Office of Emergency Services, State Emergency Plan, May 1998**: Defines the emergency management system used for all emergencies in California. The plan describes the state government's response to disasters, including the response of all levels of government and certain private-sector organizations to all natural and human-made emergencies that threaten life, property, and the resources of California. It focuses on the basic requirements for disaster management and coordination under SEMS. It is intended to be used in conjunction with city, county, operational areas, and state agency plans and associated standard operating procedures. The State Emergency Plan recognizes and designates CDHS as the lead State department for public health response.

- **Federal Emergency Management Agency, National Response Plan**, **December 2004:** An all-discipline, all-hazards plan that provides a single, comprehensive framework for managing domestic incidents. It provides the structure and the mechanisms for coordinating delivery of federal assistance and resources to augment efforts of state, local, and tribal governments overwhelmed by a major disaster or emergency. It includes 32 signatory partners, including numerous federal departments, the American Red Cross, the National Voluntary Organizations Active in Disaster, and other organizations. It supports implementation of the Robert T. Stafford Disaster Relief and Emergency Assistance Act and for exercising direct federal authorities and responsibilities. For events that rise to the level of an Incident of National Significance, it provides operational or resource coordination for federal support to on-scene incident command structures.

- **Regional Disaster Medical and Health Coordinator Emergency Plans**: These plans are prepared by each Regional Disaster Medical/Health Coordinator to describe their local disaster response roles.

- **Health Officer Practice Guide for Communicable Disease Control in California, December 12, 2005:** A compilation of statutes, examples, and interpretations by local public health officials, county counsels, and others to provide a guide for local planning and actions during a public health emergency. The document can be found on the California Department of Health Services website at www.dhs.ca.gov/EPO.

- **National Strategy for Pandemic Influenza, November 2005 Homeland Security Council:** Establishes the national perspectives on planning and preparedness for addressing a pandemic influenza outbreak on the national, state, and local levels.

- **Implementation Plan for the National Strategy for Pandemic Influenza, May 2006, Homeland Security Council:** Clarifies the roles and responsibilities of governmental and non-governmental entities and provides preparedness guidance for all segments of society.

EMERGENCY MANAGEMENT ORGANIZATION

The CDHS Pandemic Influenza Preparedness and Response Plan is an emergency-specific annex to the CDHS *Public Health Emergency Response Plan and Procedures*. The plans describe the relationship of CDHS to the state emergency response structure and the roles and responsibilities of CDHS organizational units. Coordination of the CDHS organizational units will be through the CDHS representatives in the Joint Emergency Operations Center (JEOC). This section describes the emergency management structure that CDHS will implement for pandemic influenza preparedness and response.

The CDHS Joint Advisory Committee on Public Health Preparedness serves as the federally-required coordinating committee on pandemic influenza issues. The CDHS Joint Advisory Committee on Public Health Preparedness advises CDHS on the formulation of policy and multi-agency preparedness and planning prior to a pandemic influenza event. This group will advise on preparedness activities and efforts as outlined in the plan. At the discretion of the Director, members of the CDHS Joint Advisory Committee on Public Health Preparedness may be included within the Multi-Agency Coordination group during an emergency. CDHS may convene technical consultants or other ad hoc advisory groups as needed to address specific issues.

CDHS is the lead state department for the State's public health component of the pandemic influenza response. In this role, CDHS will communicate directly with other state agencies and coordinate activities through the Governor's Office of Emergency Services. CDHS will work closely with EMSA in coordinating the medical response. CDHS has primary responsibility for activating the pandemic influenza response at the level appropriate to the specific phase of a pandemic. Within CDHS, the structure of the response organization will include a Disaster Policy Council, the JEOC, and coordination within individual programs and organizational units. The relationships of various groups are described below.

- **CDHS Directorate:** The Director of CDHS is responsible for the CDHS pandemic response. The CDHS Director will:
    - In coordination with the Emergency Preparedness Office (EPO), activate the CDHS emergency management organization as appropriate;
    - Activate the CDHS Disaster Policy Council to recommend high-level policy decisions and ensure that all CDHS organizational units implement these decisions;
    - Provide policy direction to emergency management groups and other state and local agencies detailed in this plan;
    - Ensure that all necessary CDHS resources are directed to respond to the emergency; and

- Maintain continuity of CDHS management and operations through a clear command authority.

- The **Disaster Policy Council** serves as an advisor to the Directors of CDHS and EMSA on policy issues related to a response to a pandemic influenza. It is activated by, and works under, the Director of CDHS and the Director of EMSA. In addition to the Directors of CDHS and EMSA, the Disaster Policy Council is composed of the State Public Health Officer and other CDHS executive staff, and recommends high-level policy decisions that govern pandemic influenza response and recovery activities.

- A **Multi-Agency Coordinating Group** is established when multiple disciplinary or jurisdictional areas are involved and incident management and policy coordination is required. The Multi-Agency Coordinating Group will be composed of the CDHS Director, the State Public Health Officer, members of the CDHS Joint Advisory Committee on Public Health Preparedness and other principals (or their designees) from organizations and agencies with direct incident management responsibilities or substantial incident management support or resource responsibilities. The Multi-Agency Coordinating Group will function as an advisory group to the JEOC. The Multi-Agency Coordinating Group will:

  - Ensure that each agency involved with incident management activities is providing appropriate situational awareness and resource status information;

  - Establish priorities between jurisdictions for acquiring and allocating resources in concert with those priorities, and identifying future resources requirements;

  - Coordinate and resolve policy issues arising from the incidents; and

  - Provide strategic coordination as required.

- The **Joint Emergency Operations Center** of CDHS and EMSA coordinates state-level medical and health response and resources, provides a location designed to facilitate the acquisition of public health and medical personnel, medical supplies, pharmaceuticals, and equipment on the request of an affected local area or region, and coordinates resource acquisition and support for field emergency response activities. The JEOC coordinates with Governor's Office of Emergency Services at the State Operations Center or Regional Emergency Operations Centers, as appropriate. Additionally, the JEOC ensures information flow to CDHS organizational units and other state agencies, and ensures coordination and information flow with federal agencies, local health departments, tribal entities, healthcare organizations, and other providers of medical care, facilities, and supplies. The JEOC is staffed by representatives from CDHS and EMSA involved in the response. However, program activities occur within the responsible organizational units. For programs located at the Richmond Campus, the Richmond Coordination Center serves as the physical

location of the program's response. This includes the Division of Communicable Disease Control (DCDC) as the lead CDHS program division on pandemic influenza planning and response (see CDHS DCDC below). An organizational chart for the JEOC during a pandemic influence response is shown in Figure 1.1.

- The **Risk Communication Team** consists of the Office of Public Affairs, the EPO Risk Communication Section, and representatives from the Division of Communicable Disease Control (DCDC). This team works collaboratively to provide all aspects of needed public information and support to local health departments. During activation, the Office of Public Affairs maintains its lead role in providing information to CDHS Executive Staff, California Health and Human Services Agency, the Governor's Office, Legislature and the news media. The Risk Communication Team coordinates CDHS' overall response with other organizational units in CDHS, local health departments, and the Governor's Office of Emergency Services Joint Information Center. The Risk Communication Team also provides lead response on the CDHS EPO website and issues appropriate California Health Alert Network (CAHAN) alerts, fact sheets, translations of materials, and hotline and support materials as part of an overall public information campaign.

DIVISION AND PROGRAM RESPONSIBILITIES FOR PANDEMIC RESPONSE

The following CDHS divisions and programs will have active and direct roles during any pandemic influenza event.

- The **CDHS Division of Communicable Disease Control (DCDC)** is the lead CDHS division during a pandemic influenza. The DCDC Division Chief will:

    - Manage or designate responsibility to DCDC staff to assist in developing an Action Plan in coordination with the JEOC and involved divisions, such as the Licensing and Certification Division and EPO, and will ensure DCDC's implementation of the Action Plan;

    - Provide DCDC liaisons to participate in the JEOC and ensure coordination of activities;

    - Ensure activation of all elements of the Pandemic Influenza Preparedness and Response Plan that are within the scope of DCDC, including the Richmond Coordination Center, and provide overall coordination among the activities composing the DCDC response; and

- In coordination with EPO, ensure appropriate coordination and communication with other states and Baja California through the California Office of Binational Border Health and the Early Warning Infectious Disease Surveillance office, and with tribal entities.

- The **CDHS Viral and Rickettsial Disease Laboratory Branch (VRDL)** will provide laboratory support to the CDHS Communicable Disease Control Division and to other agencies concerned with the diagnosis, prevention, and control of viral and Rickettsial infections. The Branch will assist local public health directors, physicians, and medical facilities in the treatment of viral infections and provide essential immune sera, antigens, and other reagents not available elsewhere to local health departments and medical facilities to support their viral diagnostic services.

- The **CDHS Immunization Branch** will assist with surveillance, prevention, and control of vaccine-preventable diseases, including seasonal and pandemic influenza.

- The CDHS **DCDC Pandemic Influenza Work Group (PIWG)** is composed of the lead for pandemic influenza planning, the Chiefs of Immunization Branch, Viral & Rickettsial Disease Lab, Infectious Diseases Branch, and provides expert technical consultation and advice to DCDC on pandemic influenza containment issues.

- The **CDHS DCDC Field-based Pandemic Influenza Technical Specialist or Rapid Assessment Teams** (composed of two Field-Based Pandemic Influenza Technical Specialists, typically a physician and a nurse or epidemiologist) may be deployed to provide technical consultation on pandemic influenza control tactics to the Operational Area or Regional Emergency Operations Center planning-intelligence branch(es) or directly to the local health officer. Field Technical Specialists and Liaisons remain under the supervision of the Richmond Coordination Center but do not supersede Operational Area or Regional Emergency Operations Center management.

- The **CDHS Emergency Preparedness Office** (EPO) is responsible for coordinating CDHS' emergency preparedness and response activities, including the 24-hour executive duty officer program, to ensure that CDHS is prepared to respond to a pandemic.

- The **CDHS Emergency Pharmaceutical Services Unit (EPSU)** will be responsible for procuring and distributing vaccines and antiviral drugs that are made available to the State.

- The **CDHS Food, Drug, and Radiation Safety Division** will coordinate the holding and control of appropriate drugs and medical supply stocks that are intended for wholesale distribution, if the appropriate Governor's Standby Order has been implemented.

- The **CDHS Licensing and Certification Division** is responsible for regulating and promoting the highest quality of medical care in community settings and facilities. Healthcare surge capacity will be a key element of the response to pandemic influenza. The Licensing and Certification Division plays a key role in response activities and in the field working with licensed facilities on beds, staffing, and medical equipment needs to respond to pandemic influenza patients.

- The **CDHS Health Information and Strategic Planning Division's Office of Vital Records** will assist local coroner operations during a pandemic through the provision of emergency supplies of death certificates and disposition forms and provide training in their use.

- The **CDHS Division of Chronic Disease and Injury Control's Epidemiology and Prevention for Injury Control Branch** will develop, maintain, and implement epidemiologic surveillance protocols during the pandemic, in coordination with the CDHS Division of Environmental and Occupational Disease Control, to determine disaster-related morbidity and mortality.

- The **CDHS Division of Environmental and Occupational Disease Control** is responsible for protecting the public from health effects of chemical and hazardous materials and will provide occupational medicine and toxicology consultation to Cal/OSHA and other agencies during a pandemic.

- The **CDHS Laboratory Science Division** is responsible for providing laboratory technical services to support emergency operations of CDHS laboratories, to assure that reliable environmental and public health laboratory services are available to help assess the damage caused by the disaster, and to ensure that reliable clinical and public health laboratory services and blood bank services are available to help diagnose and treat the injuries, diseases, and medical conditions of human victims of the disaster.

California Department of Health Services

CDHS Organization Chart for Pandemic Influenza

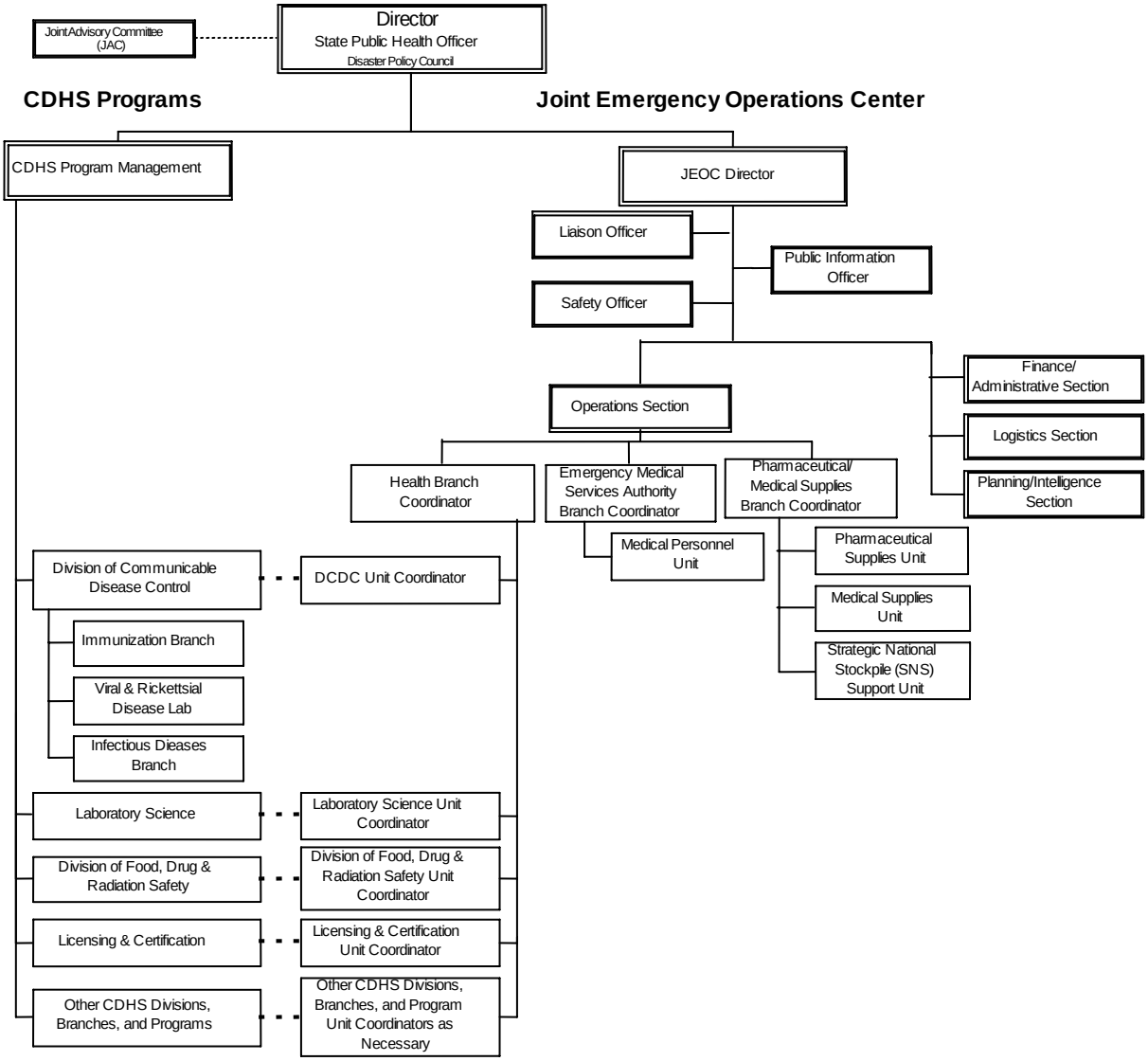


Figure 1.1 The CDHS Organizational Chart for Pandemic Influenza. Solid lines denote official relationships and information flow. Dotted lines denote unofficial information channels and notification.

CONCEPT OF OPERATIONS

Synopsis of Operational Priorities

CDHS operational priorities in response to a potential pandemic are to:

- Ensure rapid and early detection of a novel virus;
- Confirm identity or type of a novel virus by laboratory identification;
- Identify the exposure source of the outbreak and the population at risk;
- Control and contain the spread of influenza through pharmaceutical and non-pharmaceutical community containment strategies, including isolation, quarantine, infection control, antiviral treatment and prophylaxis, and, if available, vaccination;
- Manage and disseminate accurate information for scientific, resource, and policy decisions in public health and healthcare delivery settings;
- Disseminate information to enlist public support and cooperation and enable personal, community, and business-based preparedness and response;
- Track and respond to subsequent pandemic influenza waves;
- Coordinate state and federal activities with local public health partners; and
- Coordinate the medical and healthcare response.

CDHS may mobilize staff in all of its divisions, branches, and programs during an emergency to perform duties outside their normal roles and work hours.

These concepts and activities are further described in the following chapters and appendices to the plan.

Operational Priorities by Pandemic Phase

WHO will designate the global pandemic phase, using the phases outlined in the Introduction of this plan. CDC, in coordination with WHO, will designate the U.S. pandemic phase. CDHS will adopt and function under the U.S. phase. The global and U.S. phases may differ. Because of the nature and impact of a pandemic, different operational priorities will pertain in different pandemic phases (Table 1.1).

Table 1.1: Pandemic Phase Operational Priorities

Pandemic Phases	Operational Priorities
Interpandemic period	
Phase 1	Strengthen pandemic influenza preparedness at the state and local levels
Phase 2	Minimize the risk of transmission from birds to humans; coordinate with the California Department of Food and Agriculture regarding infected bird populations and the California Department of Food and Agriculture's possible request for state of emergency proclamation; ensure rapid detection and reporting of the first occurrence of the novel virus in humans. Coordinate with the California Department of Fish and Game regarding migrating wild bird populations and potential infections.
Pandemic alert period	
Phase 3	Continue to strengthen preparedness at the state and local levels. Ensure rapid characterization of the new virus subtype and early detection, notification, and response to additional cases and enhance surveillance.
Phase 4	Contain the new virus within limited foci or delay spread to gain time to implement preparedness measures, including vaccine development.
Phase 5	Maximize efforts to contain or delay spread, to possibly avert a pandemic, and to gain time to implement pandemic response measures.
Pandemic period	
Phase 6	Minimize the impact of the pandemic, while striving to maintain routine provision of public health and healthcare delivery.
Postpandemic Period	
Mitigation and Recovery	Continue public health actions, evaluations and research, public communications, mental health activities, surveillance, and preparations for reoccurring or additional outbreaks

Planning and Preparedness

Before sustained human-to-human transmission of a novel influenza strain, CDHS is responsible for ongoing preparedness activities, including:

- Convening advisory groups to advise CDHS on implementation of the Pandemic Influenza Preparedness and Response Plan;

- Identifying public and private sector partners needed for effective planning and response;

- Developing the Pandemic Influenza Preparedness and Response Plan including conducting surveillance, laboratory testing, case management and treatment; obtaining and distributing vaccine and antivirals; preventing the spread of disease in the community; conducting healthcare facilities planning; and communicating to the public;

- Integrating pandemic influenza planning with other planning activities conducted under CDC and Health Resources and Services Administration bioterrorism preparedness cooperative agreements;

- Coordinating with local health departments to ensure development of local plans, as called for by the state plan, and providing planning resources, such as templates and training;

- Developing data management systems needed to implement components of the plan;

- Identifying and training CDHS staff to manage and facilitate response during a long-term emergency;

- Assisting local health departments in exercising plans and coordinating within their jurisdiction, with tribal entities, and with adjoining jurisdictions and states;

- Enhancing the influenza-like illness surveillance efforts of local health departments and tribal entities through training and laboratory support;

- Developing guidelines for healthcare facilities and healthcare delivery organizations related to planning, preparedness, and response;

- Specifying the activation thresholds for the JEOC;

- Operating the JEOC;

- Evaluating local health department and tribal entity pandemic influenza plans;

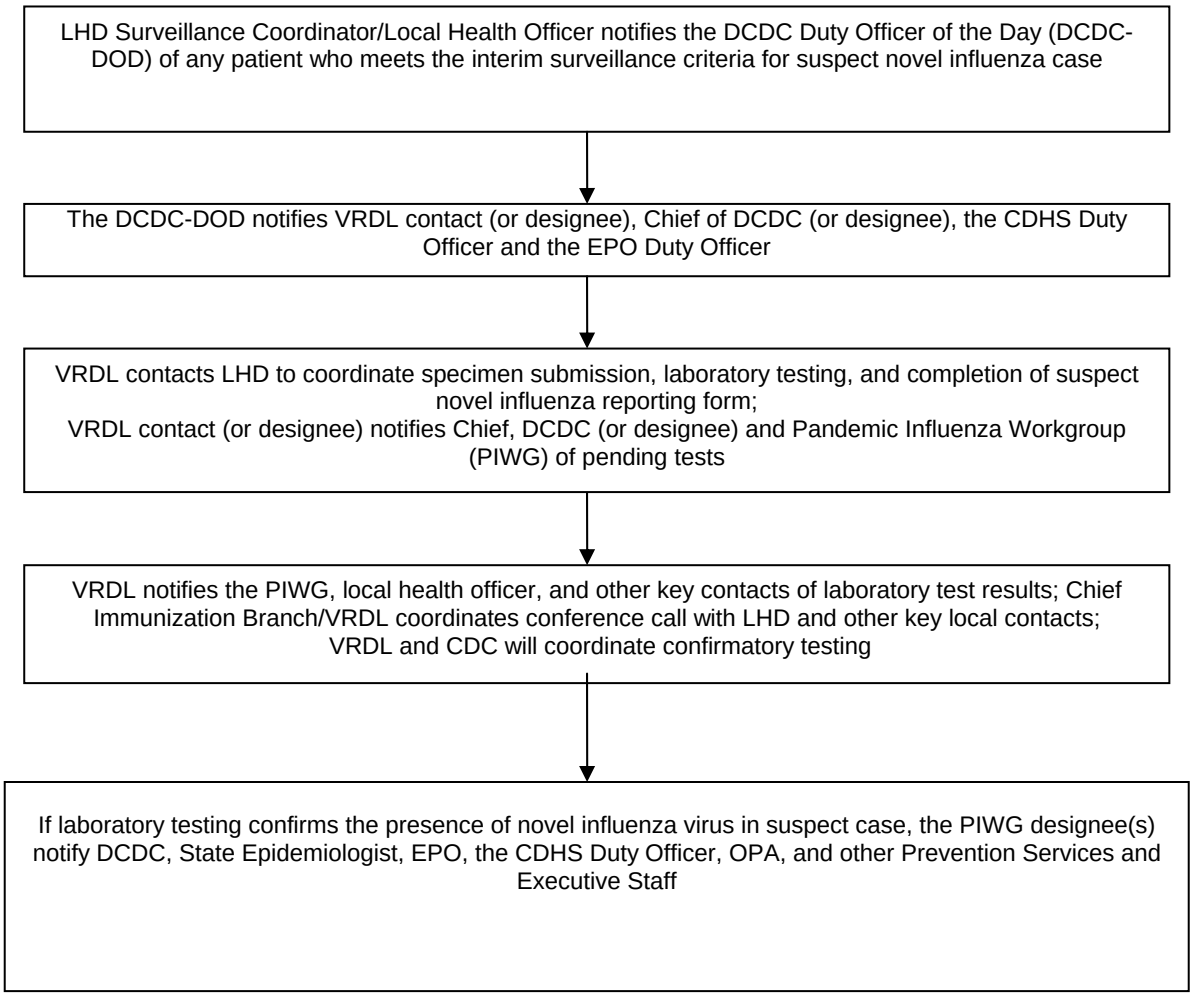
- Providing guidance to the private sector regarding continuity of operations planning; and

- Planning and coordinating public health activities with other states and Baja California through the California Office of Binational Border Health and the Early Warning Infectious Disease Surveillance office.

Emergency Response Notification and Activation Procedures

Medical or public health authorities may detect the first human case of novel influenza virus disease in California through the clinical evaluation and laboratory confirmation of persons presenting with influenza-like illness or upper respiratory disease. (Influenza-like illness is defined as a fever above 100°F *and* a cough or sore throat in the absence of a known cause other than influenza.)

CDHS receives updated national surveillance recommendations from CDC via the Health Alert Network. The DCDC PIWG reviews these surveillance recommendations, provides any needed technical clarifications or revisions for application to California, and distributes recommendations to local health departments, medical providers, and hospital-based infection control practitioners by e-mail and through CAHAN. Local health departments distribute recommendations to individual physicians and other providers through CAHAN or their own emergency communication mechanisms. If CDC recommendations are not forthcoming, the DCDC PIWG develops interim surveillance recommendations and distributes them through e-mail and CAHAN. The following flow chart illustrates CDHS' notification and initial activation procedure in response to a novel influenza virus or a suspect novel human influenza case in California.



The first case of laboratory-confirmed novel influenza virus human infection in California or elsewhere in the United States, or evidence of sustained human-to-human transmission anywhere in the world, will result in activation of the relevant components of CDHS emergency management organization and may trigger a Governor's proclamation of a state of emergency. The scale of CDHS activation will be situation-specific and will be determined by the CDHS Director in consultation with the State Public Health Officer, DCDC, EPO, and the Disaster Policy Council.

CDHS will notify the Governor's Office of Emergency Services of the activation of the JEOC. During initial activation of the JEOC, the JEOC Director will convene a conference call with key JEOC managers and DCDC representatives, including the PIWG, to assess the situation and determine the appropriate public health actions and priorities.

DCDC will convene a conference call with all local health departments, key state agencies, and other local contacts within one day of a positive laboratory confirmation of human infection with a novel influenza virus. DCDC will implement planned activities and may deploy a pandemic influenza assessment team to the location of the first case of infection to assess the situation and assist in case investigation. These teams report intelligence and situation assessments directly to DCDC and the JEOC.

Actions to Control the Pandemic and Responsible Parties

The key functional areas of the pandemic influenza response are surveillance and epidemiologic investigation, vaccine and antivirals operations, non-pharmaceutical community containment, surge capacity, infection control guidance to healthcare facilities, and risk communications.

During a pandemic, local health departments are responsible for:

- Conducting primary surveillance and reporting of cases;
- Conducting primary case investigation and contact tracing;
- Conducting primary laboratory analysis and confirmation of influenza;
- Identifying sources of disease and causes of disease spread;
- Initiating education and information to prevent spread of disease;
- Providing or coordinating vaccination and prophylaxis, and other means of preventing spread;
- Protecting communities through legal orders and enforcement of those orders;
- Coordinating with other public health agencies at the local and state level;
- Requesting assistance from other local and state agencies; and
- Informing and educating partner agencies and the public on public health guidance and actions needed to reduce and slow the spread of disease.
- Identification and coordination of alternate care sites.

CDHS will be responsible for the following actions:

- Assessing the need for enhanced surveillance in both affected and unaffected localities and activating revised surveillance protocols;
- Activating enhanced influenza surveillance strategies that are coordinated with national surveillance objectives;
- Activating reference laboratory testing, ensuring appropriate capacity, and providing guidance to local laboratories;
- Assessing the need for, and activating re-prioritized laboratory testing protocols;

- Activating and deploying specialists and liaisons, or Rapid Assessment Teams, comprising state staff, to selected locations in the field;

- In coordination with the CDHS Joint Advisory Committee on Public Health Preparedness' established subcommittee, titled the CDHS Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization Strategies, and under general authorities, developing a dynamic list of treatment and prophylaxis recommendations for a novel virus including target recipients;

- Disseminating case and contact management protocols to ensure suspect cases are promptly identified and isolated, and contacts are located, quarantined, and monitored for symptoms;

- Identifying priority vaccine recipients and ensuring appropriate vaccine storage, handling, and administration;

- Distributing federally-supplied vaccine, according to California's Strategic National Stockpile Plan, to targeted geographic areas and recipients;

- Activating infection control procedures and disseminating guidance to minimize transmission of influenza in homes, the community, and healthcare facilities;

- Invoking state legal authorities to increase or support availability of additional acute care beds and alternate care sites, including licensure of and infection control in healthcare facilities;

- Invoking state legal authorities, such as modifying licensing requirements, to support the availability of surge clinical and hospital staffing;

- Recommending to local authorities the most feasible, effective, and enforceable methods of isolation and quarantine to prevent the spread of influenza;

- Invoking isolation, quarantine, or non-pharmaceutical community containment requirements using state legal authorities, and coordinating with federal authorities on measures to prevent the interstate spread of influenza;

- Coordinating with federal and local authorities to ensure that communications with the public are consistent, accurate, address anxieties, alleviate unwarranted concerns or distress, and enlist cooperation with necessary control measures;

- Promoting self-protective behaviors to California communities in multiple languages and formats by developing consistent messages and materials for distribution through local health departments, tribal entities, response partners, and others;

- Providing training, including just-in-time training, to build public health and healthcare capacity to respond;

- Implementing Governor's Standby Order to hold and control drugs and medical supplies intended for wholesale distribution, obtaining necessary inventories, and coordinating the distribution of assets to the designated locations;

- Organizing and releasing state and federal public health and medical response assets (in conjunction with local officials) including personnel, drugs, and medical supplies, including assets from the federal Strategic National Stockpile;

- Assessing the need for and recommending step-down and recovery operations;

- Activating post-event surveillance to monitor the pandemic;

- Continuing vaccine programs, if available, to maintain or increase immunity in the population; and

- Communicating and coordinating pandemic influenza response activities, with representatives from other states and Baja California.

Mitigation

During a pandemic, large-scale disruption of all sectors of society is likely. Mitigation activities are important elements of preparedness and provide a critical foundation across the incident management spectrum, from prevention through response and recovery. This plan incorporates mitigation activities throughout the pandemic phase responses. Activities that may mitigate the impact of a pandemic include the following:

- Educating the public on respiratory and hand-washing hygiene and what to expect during a pandemic;

- Planning for continuity of operations to handle absenteeism;

- Planning for inventory scarcity and disruption of essential supplies;

- Developing pharmaceutical solutions and distributing vaccines and antiviral medications. Vaccines will be unavailable or in short supply for at least six months and antivirals will be exhausted quickly with uncertain replacement supplies during a pandemic; and

- Implementing non-pharmaceutical community containment measures such as wearing masks, staying home if sick, and canceling school and public events.

Recovery

Unlike other natural disasters, an influenza pandemic may last for two to three years and occur in several waves. Recovery begins while the pandemic is still in progress and continues between waves and after the pandemic. The following activities are important aspects of recovery:

- Providing detailed retrospective characterization of the pandemic;
- Evaluating the efficacy of containment measures and emergency management strategies;
- Assessing the effectiveness of vaccines and antivirals;
- Preventing or minimizing subsequent waves of influenza by using current vaccine or antiviral resources; and
- Incorporating mental health messages into public communications to reduce post-traumatic stress disorders.

After a pandemic, CDHS will review and critique of the response activities in this plan with staff and other organizations and agencies. The review will result in an after-action report with recommendations to improve future preparedness.

Chapter 2.

PANDEMIC INFLUENZA SURVEILLANCE AND EPIDEMIOLOGY

INTRODUCTION

Global Influenza Surveillance

The World Health Organization (WHO) Global Influenza Surveillance Network is composed of four WHO Collaborating Centers and 112 institutions in 83 countries, which are recognized by WHO as WHO National Influenza Centers. Annually, the National Influenza Centers collect more than 175,000 patient samples and submit around 2,000 viruses to the four Collaborating Centers for antigenic and genetic analyses. The WHO Influenza Surveillance Network also serves as a global alert mechanism for the emergence of influenza viruses with pandemic potential.

National Influenza Surveillance

In the United States, the Centers for Disease Control and Prevention coordinates national influenza surveillance. National influenza surveillance consists of five components:

- Laboratory surveillance;
- Outpatient influenza-like illness surveillance;
- Pneumonia- and influenza-related mortality surveillance;
- Influenza-associated pediatric mortality surveillance; and
- Determination of relative influenza activity in individual states.

CDHS Influenza Surveillance

Influenza-Like Illness and Novel Influenza Virus Surveillance

Influenza is not a reportable disease in California because of the large number of cases that occur each year with a non-specific clinical presentation and no routine laboratory confirmation. However, CDHS collaborates with academic, public, and private institutions to obtain information from multiple sources about disease activity. During the influenza season (Week 40 through Week 20), through a collaborative effort between the Viral and Rickettsial Disease Laboratory (VRDL), Immunization Branch, and Infectious Diseases Branch, CDHS monitors influenza illness activity using the following surveillance systems (see Appendix A):

- Hospitalizations for pneumonia and influenza (Northern and Southern California Kaiser Permanente);
- Antiviral prescription data (Northern and Southern California Kaiser Permanente);
- Outpatient influenza-like illnesses (CDC Influenza Sentinel Providers);
- California emergency department visit data (California Emergency Physicians);
- Severe pediatric influenza and pediatric influenza-associated deaths;
- Surveillance of respiratory outbreaks in long-term care facilities;
- Surveillance for human avian influenza;
- Surveillance for vaccine adverse events; and
- Influenza-like illness surveillance along the California-Baja California border through the Early Warning Infectious Disease Surveillance and Border Infectious Disease Surveillance Programs.

Influenza Laboratory Surveillance

- **Sentinel Laboratories** provide data on the number of laboratory-confirmed influenza and other respiratory virus detections and virus isolations. Nineteen laboratories report these data weekly.
- The **Respiratory Laboratory Network** encompasses 22 local public health laboratories in California. Of these, 20 Respiratory Laboratory Network laboratories offer enhanced diagnostic testing for several respiratory pathogens, including influenza A and B viruses,

respiratory syncytial virus, parainfluenza virus, and adenovirus. All 22 Respiratory Laboratory Network laboratories offer polymerase chain reaction (PCR) testing for influenza A and B.

- **CDHS Viral & Rickettsial Disease Laboratory (VRDL)** serves as a statewide reference laboratory that offers diagnostic testing for influenza using isolation, PCR, and serologic testing.

The Division of Communicable Disease Control (DCDC) has a Pandemic Influenza Work Group (PIWG) consisting of representatives of VRDL, Immunization Branch, and Infectious Diseases Branch. The team meets weekly throughout the influenza season to review surveillance data, discuss the level of influenza activity, review individual cases and outbreaks, review vaccine supply distribution and allocation, work on communication activities, coordinate efforts with the Office of Public Affairs and Emergency Preparedness Office Risk Communication Section, and assign tasks when action is needed.

CDHS Influenza Epidemiologic Investigations

CDHS, in collaboration with local health departments, will initiate epidemiologic investigations to identify how suspected human cases of novel influenza virus became infected, assess the clinical impact of the disease, and determine the risk that infected persons or their environment may represent for others. CDHS will also initiate contact investigations to prevent further transmission, identify potential new cases, and provide appropriate prophylaxis or treatment. Based on these epidemiologic investigations, preventive measures, including non-pharmaceutical containment strategies, may be identified or revised, and specific actions (e.g., identification and prophylaxis treatment of contacts) evaluated and implemented.

OBJECTIVES

The objectives of CDHS pandemic influenza surveillance are to:

- Monitor the emergence of a novel influenza virus in human populations and detect the first appearance of a novel influenza virus in California;
- Describe the epidemiologic and clinical features of an influenza outbreak; and
- Provide critical surveillance data and facilitate response activities.

The objectives of CDHS pandemic influenza epidemiology are to:

- Ensure that suspect novel human influenza cases are isolated and that the sources of exposure (animal vs. human) are determined in the pandemic alert and early phases of a pandemic; and

- Conduct epidemiologic investigations of suspect human influenza cases to:

    - identify at-risk populations and current clinical characteristics of disease;

    - assess likely human-to-human transmission;

    - evaluate phase-specific control measures; and

    - characterize and assess impact of pandemic influenza on the California population.

ASSUMPTIONS AND PLANNING PRINCIPLES

Influenza Illness Surveillance

- An effective statewide pandemic influenza surveillance system requires a well-functioning, interpandemic influenza surveillance system.

- Surveillance needs will expand and change as an influenza pandemic evolves from the initial stages (i.e., when a novel influenza virus is first identified in one or more persons), to a pandemic (i.e., with efficient human-to-human transmission). Surveillance needs will differ, depending on where the disease has been identified, whether there is coexisting disease among poultry or other animals, whether and how efficiently transmission occurs between people, and whether disease outbreaks have occurred in the United States or other countries.

- Surveillance data will be critical to help guide implementation of control measures, such as restricting travel, closing schools, canceling public gatherings, initiating antiviral and vaccine usage in target groups, assessing the impact of a pandemic on the healthcare system, and assessing the social and economic impact on society.

- During a pandemic, stakeholders, the media, and the public will demand timely surveillance data.

- California shares many social and economic ties with Baja California, Mexico. There are more than 200 million border crossings a year. When individuals with an infectious

disease or their contacts cross the international border, binational cooperation is necessary for public health follow-up. Close collaboration between California and Baja California influenza surveillance systems is essential to monitor influenza activity and guide coordinated response strategies in the border region.

- In the interpandemic period and early stages of a pandemic, before community transmission is established, CDHS and local health departments will monitor individual cases of suspected and confirmed novel virus infection and collect relevant demographic and clinical information. Once sustained community transmission is established, monitoring suspected and confirmed cases may become overwhelming. CDHS and local health departments may only collect aggregate numbers of suspected and confirmed cases by local health jurisdiction, as well as other important morbidity and mortality markers, such as numbers of hospitalizations and deaths.

- Once a pandemic is under way, supplies of rapid antigen testing and reagents for immunofluorescence assays and PCR likely will be depleted. At this stage, surveillance for novel virus infection will rely primarily on clinical diagnoses made in outpatient clinics, emergency departments, inpatient wards, and intensive care units, with assistance from the local health departments.

Pandemic Influenza Epidemiologic Investigation

- In the pandemic alert period and in the early phases of the pandemic, identifying the source of infection (animal vs. environment vs. human) of new cases will be a critical activity that will support decisions about containment strategies. Once the pandemic is under way, the need for such investigations will be determined.

- The types of epidemiologic investigations conducted (i.e., those addressing clinical characteristics, risk factors, the probability of transmission among humans, treatment efficacy studies) will vary during different phases of the pandemic.

CDHS Pandemic Response Action Steps

WHO Phase 1 and Phase 2

Interpandemic Period: No novel influenza subtypes have been detected in humans, but a novel subtype that has caused human infection may be present or circulating in animals.

Influenza Illness Surveillance

CDHS will:

- Continue all interpandemic surveillance activities as described above and in Appendix A;
- Encourage influenza sentinel providers to perform year-round reporting of influenza-like illness activity;
- In conjunction with local public health laboratories, explore developing a laboratory-based surveillance system for cases of severe unexplained pneumonia;
- In conjunction with local health departments, explore developing an enhanced surveillance system for influenza-like illnesses in sentinel school-based clinics and health offices;
- In conjunction with local health departments, explore developing an enhanced surveillance system for pneumonia and influenza-associated deaths;
- In conjunction with local health departments, work closely with healthcare organizations and healthcare providers to implement active surveillance in emergency departments, inpatient wards, and intensive care units;
- Encourage the use of influenza rapid diagnostic tests, immunofluorescence assays, and PCR to detect the first case(s) of novel virus infection in California, and target containment strategies, such as isolation and quarantine, contact tracing, and use of limited vaccine and antivirals in the populations at risk during the interpandemic period and early stages of a pandemic, before community transmission is established;
- Explore the possibility of assessing rates of hospitalization for pneumonia and influenza activity in sentinel hospitals, (i.e., community hospitals and children's hospitals);

- Request local health departments to report any suspect avian influenza cases and forward clinical specimens for concurrent testing;

- Expand the capacity for novel virus testing among sentinel local public health laboratories, including providing training, technical assistance, and reference or validation testing. Request sentinel local public health laboratories to report testing for any suspect avian influenza cases and to forward clinical specimens to VRDL for concurrent testing;

- Coordinate with the California Department of Food and Agriculture and California Department of Fish and Game on enhanced surveillance and reporting of novel influenza virus in poultry workers, commercial and private poultry flocks, and wild birds, to identify disease activity in animal populations and to characterize the human health threat; and

- Share influenza surveillance data and epidemiologic information in a timely manner with tribal entities, bordering states, and Baja California public health officials.

Epidemiologic Investigation

CDHS will:

- Develop and implement criteria and protocols for epidemiologic investigation of influenza outbreaks, influenza case clusters with unusual clinical presentations (e.g., unusual severity), and clusters of unexplained pneumonia;

- Enhance and expand capacity at the local and state levels to conduct case investigations and epidemiologic investigations during WHO Phases 1 through 4. These activities will include conducting an inventory of current capacity, determining current skill levels, conducting drills and exercises in case investigations, developing forecasts of future capacity needs under different pandemic scenarios, identifying gaps in capacity, and conducting epidemiologic investigations during WHO Phase 1 and Phase 2;

- In conjunction with local health departments, evaluate and implement an outbreak management system to assist with case management, case ascertainment, case reporting, surveillance, and data analysis;

- Develop protocols that clearly designate who will conduct epidemiologic studies in Phases 3 through 6 and coordination between local, state, and federal investigations; and

- Identify funding and training strategies to ensure that epidemiologic capacity at the state and local levels is consistent with current and future needs. Collaborate with CDC and

Baja California health officials in the epidemiologic investigation of binational influenza cases and outbreaks.

WHO Phase 3 and Phase 4

Pandemic Alert Period: Human infection with no or very limited human-to-human transmission

Influenza Illness Surveillance

CDHS will:

- On laboratory confirmation of the first case of novel influenza virus in California, develop and distribute guidance to local health departments on surveillance, case detection, contact tracing, and infection control. CDHS DCDC will coordinate disease control activities and provide technical assistance to local health departments with any confirmed cases of novel influenza virus infection;

- Actively monitor, and implement as necessary, any changes in recommendations and guidelines for surveillance and diagnostic testing from CDC (e.g., revision of the case definition, screening criteria, case report forms, or diagnostic testing algorithms), and post a case screening form and case report form for laboratory confirmed cases to the California Influenza Surveillance Project (CISP) website at: http://www.dhs.ca.gov/ps/dcdc/vrdl/html/flu/fluintro.htm;

- Communicate with local health departments via weekly electronic communications, *CD Brief*, the VRDL California Influenza Surveillance Project website, and conference calls to share information on surveillance criteria, case management, specimen collection, and appropriate testing;

- Issue guidelines for managing suspect novel influenza cases, including infection control guidelines, guidelines for collecting and shipping specimens for influenza A (H5N1) diagnostics, laboratory biosafety guidelines for handling and processing specimens of novel influenza A, and specimen submittal forms will be posted on the VRDL California Influenza Surveillance Project website: www.dhs.ca.gov/ps/dcdc/VRDL/html/FLU/fluintro.htm;

- Work with local health departments to detect and monitor persons who have recently traveled to areas where the novel virus has been identified and who present with clinical illness consistent with influenza. Provide technical assistance and guidance to assess and report suspect cases of novel virus infection;

- Encourage all influenza sentinel providers to report data year-round and educate sentinel providers of the enhanced surveillance activities, including submission of specimens to VRDL, and of the need to report suspect cases to their local health department for further evaluation and testing;

- Recruit additional sentinel physicians to report influenza-like illness activity, to collect respiratory specimens, and to submit them to VRDL for testing;

- Maintain all other existing enhanced surveillance systems;

- Explore recruiting pharmaceutical vendors or large pharmacy chains to report the number of antiviral prescriptions filled. Explore the use of Medi-Cal pharmacy paid claims data to determine antiviral drug usage;

- Encourage reporting of all suspect human cases of the novel influenza virus or cases of clinical illness consistent with a novel influenza virus through an electronic case reporting system;

- Generate weekly reports of statewide influenza activity and distribute surveillance data to participating agencies, CDC, local health departments, Emergency Preparedness Office, Joint Emergency Operations Center Public Information Officer, and Office of Public Affairs;

- Review contingency plans to further enhance influenza surveillance if efficient person-to-person transmission of the novel virus is confirmed, including training additional personnel on surveillance, case detection, contact tracing, and infection control issues;

- Continue coordinating with California Department of Food and Agriculture and California Department of Fish and Game on enhanced surveillance and reporting of novel influenza virus detection in poultry workers, commercial and private poultry flocks, and in wild birds to identify disease activity in animal populations and to characterize the human health threat;

- Communicate current surveillance data, epidemiologic information, and changes in recommendations and guidelines for surveillance and diagnostic testing from CDC with Baja California public health officials;

- Petition for the mandatory reporting to the local health department of any instance when avian influenza testing is requested by a healthcare practitioner, including requests sent to private commercial laboratories;

- Expand capacity for novel virus testing in sentinel local public health laboratories, including providing training, technical assistance, and reference and validation testing;

- Request local public health laboratories to forward clinical specimens to VRDL for concurrent novel virus testing;

- Collaborate with commercial laboratory stakeholders who are offering novel virus testing to report any preliminary positive results for novel virus infection to either the local health department or VRDL immediately. If VRDL is notified first, VRDL will contact the local health department within 12 hours;

- Encourage submission of clinical specimens from influenza-like illness cases from all sources (public and private clinics, including sentinel providers, and hospitals) and facilitate subtyping of influenza A viruses at either the local or state level. VRDL will perform novel virus testing on all suspect cases of the novel influenza virus, and will support testing capacity at local public health laboratories;

- Communicate with CDC concerning updated diagnostic algorithms and laboratory reagents for novel virus testing (e.g., specific primers and probes), communicate results on suspect novel influenza virus cases to CDC, and expedite specimen shipping; and

- Communicate with local public health laboratories and other stakeholders via regular statewide conference calls regarding the detection and circulation of novel virus worldwide and in the United States, and provide detailed guidance on updated case definitions, diagnostic algorithms, and laboratory infection control issues. Expand capacity for novel virus testing to local public health laboratories, including providing training, technical assistance, and reference testing. Request local public health laboratories to forward clinical specimens to VRDL for concurrent novel virus testing.

Epidemiologic Investigation

CDHS will:

- In coordination with CDC, develop, distribute, and implement case management protocols to ensure that suspect human cases are promptly identified and isolated and that the source(s) of exposure (animal vs. human) are determined. Ensure protocols are distributed to local health departments and settings where cases and their contacts might be diagnosed;

- In collaboration with CDC and local health departments, conduct, direct, coordinate, or provide guidance on epidemiologic investigations of human cases to identify the populations at risk, the current clinical characteristics of disease, and the risk that infected persons or their environment may pose to others, including an assessment of likely human-to-human transmission;

- In conjunction with local health departments, develop a database or registry for case investigations, case management, case ascertainment, case reporting, surveillance, and data analysis;

- Coordinate with CDC and other partners on studies of viral shedding to determine the infectious and incubation periods for use in defining the duration of isolation and quarantine;

- Collaborate with CDC and Baja California health officials in the epidemiologic investigation of binational influenza cases and outbreaks;

- Summarize and distribute study results internally for use in assessing recommendations regarding the application and utility of non-pharmaceutical containment measures. Provide scientific review of results or identify subject matter experts for scientific review of results, as needed; and

- Monitor investigation and management resources. As resources permit, assess and enhance epidemiologic capacity to support expanded activities.

WHO Phase 5

Pandemic Alert Period With Substantial Pandemic Risk: Larger clusters but still limited human-to-human transmission; sustained community transmission is possible

The focus of surveillance during this Phase 5 is to identify the timing, location, and extent of the novel influenza virus infection in California to guide implementation of outbreak control and other response activities.

Influenza Illness Surveillance

CDHS will:

- Communicate with CDC to monitor any changes in recommendations and guidelines for surveillance and diagnostic testing, including guidance on triaging specimens for testing and choosing which isolates to send to CDC and immediately inform local health departments of new recommendations;

- Recommend and post on the California Health Alert Network (CAHAN), which subset of suspect cases of influenza-like illnesses meet the criteria for influenza testing at either the institutional, local, or the state level; if testing confirms influenza, VRDL and local public health laboratories with novel virus testing capacity will perform further testing as indicated;

- Work closely with local health departments to manage new suspect cases, provide confirmatory testing, and implement containment strategies to prevent or limit local spread (e.g., isolation and quarantine and antiviral treatment and prophylaxis);

- Provide technical assistance to guide expanded testing on specific cases that represent a risk of spread of the novel virus infection in the community, including those who have an epidemiologic link to infected cases (i.e., recent contact with a person in whom an infection is either suspected or confirmed) or who are hospitalized. Communicate with CDC concerning management, reference laboratory testing, and containment strategies in these cases;

- Communicate current surveillance criteria for cases of human novel virus infection, and the need to report data year-round and submit clinical specimens on influenza-like illness cases to sentinel providers and local health departments;

- Activate all enhanced surveillance systems to report data year-round and coordinate and communicate these activities with local health departments;

- Generate weekly reports of statewide influenza activity and make current surveillance data available to all participating agencies as well as CDC, local health departments, Emergency Preparedness Office, Joint Emergency Operations Center Public Information Officer, and Office of Public Affairs;

- Allocate additional personnel as needed to assist with surveillance activities, such as identifying information technology resources needed to assist in developing or modifying databases for influenza surveillance;

- Communicate the most current information on influenza epidemiology to Baja California public health officials;

- Maintain expanded critical laboratory testing capacity, including novel virus testing, antiviral resistance testing, neutralizing antibody assays to test for immunity to the novel virus, and egg-based culture methods to isolate novel viruses that are difficult to grow by standard culture methods; and

- Using e-mail, CAHAN, Epi-X, broadcast fax, and statewide conference calls, communicate with local public health laboratories and other stakeholders regarding the detection and circulation of novel virus worldwide and in the United States and provide detailed guidance on updated case definitions, diagnostic algorithms, and laboratory infection control issues. As the pandemic progresses and guidelines and testing algorithms are revised, VRDL will communicate these changes to local public health laboratories.

Epidemiologic Investigation

CDHS will:

- In coordination with CDC and the DCDC PIWG, review and revise case management protocols to reflect current recommendations and epidemiologic data; and

- Continue pandemic influenza-specific epidemiologic investigations and other special clinical studies.

WHO Phase 6

Pandemic Period: Increased and sustained transmission in the general population

CDHS will:

- Monitor the epidemiology and impact of the pandemic in California; and

- Sustain the capacity to perform laboratory-based surveillance because influenza viruses may undergo antigenic drift or develop resistance to antiviral agents.

Influenza Illness Surveillance

CDHS will:

- Support local health departments, public and private medical providers, hospitals, and other stakeholders to maintain surveillance efforts for cases of novel virus infection. As the pandemic progresses and laboratory services become overwhelmed, public and private medical providers and hospitals may be asked to selectively submit clinical specimens as directed by CDC. If laboratory supplies and reagents are exhausted, surveillance for novel virus infection will rely on a presumptive clinical diagnosis made by clinicians;

- Recommend discontinuing individual case reporting and request regular status reports from local health departments on cumulative statewide case counts associated with novel virus infection, morbidity, and mortality; such reports might include the number of:

    - clinically suspected cases;

    - laboratory confirmed cases;

    - persons hospitalized with a novel virus infection; and

- deaths attributed to novel virus infection.

- In collaboration with CDC and local health departments, and as resources are available, conduct special investigations to:
  - describe unusual clinical syndromes;
  - describe unusual pathologic features associated with fatal cases;
  - determine efficacy of vaccination, if vaccine is available, or antiviral prophylaxis;
  - assess antiviral effectiveness in circulating strains to help refine antiviral recommendations and target high risk groups; and
  - assess the effectiveness of non-pharmaceutical containment measures such as school and business closures.

- Determine which populations are at greatest risk, and, in conjunction with CDC, refine and revise priority groups for vaccination as vaccine availability increases;

- Generate weekly reports of statewide activity and share current surveillance data with all participating agencies including CDC, local health departments, Emergency Preparedness Office, Joint Emergency Operations Center Public Information Officer, and Office of Public Affairs;

- Communicate the most current information on influenza surveillance, epidemiology, and (potential) control efforts to Baja California public health officials;

- As resources permit, continue to encourage all participating sentinel laboratories and the Respiratory Laboratory Network to test for influenza with non-culture methods. Depending on CDC guidance, request laboratories to forward specimens to VRDL or local public health laboratories with novel virus testing capacity for further testing;

- As indicated by CDC guidance and as resources permit, characterize the strain of incoming specimens and isolates to detect antigenic drift variants and reassortant viruses that could limit the efficacy of vaccines produced against the original pandemic strain; and

- As resources permit, continue to perform testing critical to ongoing surveillance, including antiviral resistance testing and neutralizing antibody assays to test for immunity to the novel virus.

Epidemiologic Investigation

- CDHS will continue situation-specific pandemic influenza epidemiologic investigations and other special clinical studies, as warranted.

WHO Postpandemic Period

The goals of postpandemic surveillance are to:

- Provide a detailed retrospective characterization of the pandemic; and
- Evaluate the efficacy of containment measures and emergency management strategies.

CDHS, in conjunction with local health departments, will**:**

- Review death certificates statewide for influenza-related pneumonia and influenza deaths;
- Collaborate with the CDC and other partners on retrospective studies of vaccine and pharmaceutical containment measure efficacy;
- Conduct retrospective validation studies of influenza illness reporting;
- Provide frequent updates to the Joint Emergency Operations Center for tracking and monitoring of postpandemic activities; and
- Conduct a retrospective assessment of cross-border coordination with Baja California public health officials.

Appendix A.

INTERPANDEMIC AND PANDEMIC INFLUENZA SURVEILLANCE

Global Influenza Surveillance

The WHO Global Influenza Surveillance Network was established in 1952. The network comprises four WHO Collaborating Centers and 112 institutions in 83 countries, which are recognized by WHO as WHO National Influenza Centers. (http://www.who.int/csr/disease/influenza/surveillance/en/index.html) These Centers collect specimens in their country, perform primary virus isolation, and conduct preliminary antigenic characterization. Annually, these Centers collect more than 175,000 patient samples and submit around 2,000 viruses to the WHO Collaborating Centers for antigenic and genetic analyses.

The four WHO Collaborating Centers that participate in the WHO Global Influenza Surveillance Network are located in Australia, Japan, the United Kingdom, and the United States. The Collaborating Centers perform, at no cost to WHO, antigenic and genetic analyses of isolates received from National Influenza Centers and maintain repositories of different virus strains. Newly isolated strains are shipped to WHO Collaborating Centers for high-level antigenic and genetic analysis, the result of which forms the basis for WHO recommendations on the composition of influenza vaccine for the Northern and Southern Hemisphere each year. FluNet, an Internet-based information exchange program, links national influenza centers and WHO collaborating centers throughout the world and provides easy exchange of global influenza surveillance data: http://gamapserver.who.int/GlobalAtlas/home.asp.

The WHO Influenza Surveillance Network serves as a global alert mechanism for the emergence of influenza viruses with pandemic potential. WHO is also coordinating the global response to human cases of novel avian influenza and monitoring the corresponding threat of an influenza pandemic, providing technical guidelines and information useful for the public on the webpage: http://www.who.int/csr/disease/avian_influenza/en/index.html.

National Influenza Surveillance

In the United States, CDC coordinates national influenza surveillance. National influenza surveillance consists of four components: laboratory surveillance, outpatient influenza-like illness surveillance, pneumonia- and influenza-related mortality surveillance, and determination of relative influenza activity in individual states. State and local health departments assume primary responsibility for carrying out the epidemiologic and laboratory surveillance components. Current surveillance activities include:

- **Laboratory-based surveillance**: Approximately 120 laboratories in the United States report the number and type of influenza viruses isolated each week and send specimens to CDC for antigenic and genetic analysis. CDC updates this information weekly on the CDC influenza surveillance website (www.cdc.gov/flu/weekly/fluactivity.htm).

- **The CDC Influenza Sentinel Provider Network**: A voluntary, national network of approximately 1000 medical providers reports the number of patients presenting with influenza-like illnesses, age group, and the total number of patient visits for all causes each week. CDC updates influenza-like illness visit activity weekly on the CDC influenza surveillance website.

- **U.S. Cities Mortality Reports**: Vital statistics offices from 122 U.S. cities report weekly the percentage of total deaths caused by pneumonia and influenza as recorded on death certificates.

- **Influenza-associated pediatric mortality surveillance**: Influenza-associated pediatric mortality is a newly added nationally notifiable condition. Laboratory-confirmed influenza-associated deaths in children less than 18 years old are reported through the Nationally Notifiable Disease Surveillance System.

- **State and territorial epidemiologists** report their level of influenza activity each week as "widespread," "regional," "sporadic," or "no activity." CDC updates this information weekly on the CDC influenza surveillance website.

California Influenza Surveillance

Influenza is not a reportable disease in California because of the large number of cases that occur each year with a non-specific clinical presentation and no routine laboratory confirmation. However, CDHS collaborates with public, academic, and private institutions to obtain information from multiple resources about disease activity. During the influenza season (Week 40 through Week 20 of each year), CDHS Viral and Rickettsial Disease Laboratory (VRDL), Immunization Branch, and Infectious Diseases Branch jointly monitor influenza illness activity from the following surveillance systems:

- **Hospitalizations for pneumonia and influenza from Northern and Southern California Kaiser Permanente (estimated membership: 6 million persons).** This surveillance system defines "flu admissions" as inpatient hospitalizations admitted with the text field diagnoses of "flu," "influenza," or "pneumonia." The percentage of influenza admissions is defined as the number of hospitalizations fulfilling the above criteria over the total number of hospital admissions for the same day, excluding admissions for pregnancy, admissions for inpatient surgeries, labor and delivery, birth, and outpatient procedures. The baseline influenza admission percentage, reflective of year-round pneumonia admissions, is estimated to be approximately three to five percent. Influenza admissions are tracked weekly, and a summary is distributed electronically to local health departments and other public health stakeholders. CDHS posts these data to VRDL California Influenza Surveillance Project website: www.dhs.ca.gov/ps/dcdc/VRDL/html/FLU/fluintro.htm.

- **Antiviral Prescription Data (Northern and Southern California Kaiser Permanente).** Kaiser Permanente reports weekly the number of prescriptions its outpatient pharmacies fill for influenza antiviral drugs (amantadine, rimantadine, zanamivir, and oseltamivir). Baseline amantadine usage is assumed to be present year-round for disorders such as Parkinson's disease. CDHS tracks antiviral usage weekly and distributes a summary to local health departments and other public health stakeholders via the *CD Brief* and VRDL California Influenza Surveillance Project website: www.dhs.ca.gov/ps/dcdc/VRDL/html/FLU/fluintro.htm.

- **CDHS' state influenza sentinel provider surveillance coordinator:**

    - Monitors sentinel provider data weekly for completeness and errors;

    - Provides feedback and maintains weekly contact with sentinel influenza providers to encourage reporting, follow-up on unusual reports, and monitor completeness and errors;

    - Encourages year-round reporting of influenza activity from sentinel providers; and

    - Encourages sentinel providers to submit specimens for viral culture to VRDL.

- **Outpatient influenza-like illness (CDC Influenza Sentinel Providers).** California has approximately 145 sentinel providers (meeting the CDC goal of 1/250,000 population) who report the number of outpatient visits for influenza-like illnesses, age group, and total number of outpatient visits per week. CDHS tracks the percentage of influenza-like illness visits weekly and distributes a summary to local health departments and other public health stakeholders via the *CD Brief* and VRDL California Influenza Surveillance Project website: www.dhs.ca.gov/ps/dcdc/VRDL/html/FLU/fluintro.htm. Sentinel providers also receive a weekly electronic update that summarizes sentinel provider influenza-like illness activity both statewide and regionally.

- CDHS continues to recruit medical providers into the CDC **influenza sentinel provider network** in order to maintain the current ratio of one provider for every 250,000 population. California has an estimated population of 36 million people, requiring 145 sentinel providers to meet CDC recommendations. Current efforts to increase, maintain and improve sentinel provider participation include:

    - Providing influenza rapid test kits to sentinel providers who do not otherwise have laboratory diagnostic testing available (e.g., student health centers, community clinics, mobile clinics, and private clinics not associated with a hospital laboratory). In the pilot year of the program (2004-2005), CDHS recruited 50 additional sentinel providers in the first few months

    - Encouraging sentinel providers to report influenza-like illness activity to a coordinator at their local health department, who can monitor reporting and encourage sentinel providers who are not reporting. As the primary contact for the sentinel provider, the local health department coordinator reports all influenza-like illnesses in his or her county to CDHS and provides all laboratory results to the sentinel providers. Using local coordinators encourages local health departments to become involved in influenza surveillance in their region and to be viewed as the "influenza resource" for their communities.

    - Focusing recruitment efforts on counties with low ratios of sentinel providers for their populations and on types of providers underrepresented in the program. Recruitment efforts in 2004-2005 focused on pediatricians, who were underrepresented. Infants, toddlers, and school-age children are thought to be the primary population to introduce the spread of influenza into a community and may often be the first population evaluated in outpatient settings.

- **California Emergency Physicians Emergency Department Visit Data.** In 2004, CDHS began collaborating with the California Emergency Physicians and its physician practice partner, MedAmerica, to assist in monitoring influenza-like illness activity at 49 emergency departments (approximately 2 million patient visits annually) statewide. Through MedAmerica's surveillance system, "California Flu Watch," emergency physician electronic billing data is used to capture specific ICD-9 codes that may identify influenza-like illnesses, including the presence of fever plus cough, sore throat, upper respiratory illness, or nasal congestion. These data are subsequently analyzed for trends by time, age group, and regional activity. Because of the lag-time (approximately two weeks) between the emergency department visit and the compilation of the billing data, the synchronization with other influenza surveillance systems may not be timely.

- **Severe pediatric influenza and pediatric influenza–associated deaths.** CDHS conducts enhanced surveillance of children with laboratory-confirmed influenza who have been hospitalized in a pediatric intensive care unit (ICU) or who have died. Each

year, CDHS requests that infection control practitioners at the 26 hospitals in California with a pediatric ICU report any cases meeting the following definition: 1) age 0 to 17 years; 2) have influenza confirmed by laboratory testing; and 3) hospitalized in a pediatric ICU or died at any location (e.g., hospital, emergency department, home). The infection control practitioners report their cases to local health departments and CDHS. In addition, CDHS sends participating infection control practitioners and medical providers a weekly electronic update of statewide and regional activity for severe pediatric influenza and influenza-associated deaths.

- **Surveillance of respiratory outbreaks in long-term care facilities.** Outbreaks in long-term care facilities are often the first sign of influenza activity in a community. CDHS conducts enhanced surveillance for respiratory outbreaks at such facilities. Each year, CDHS sends a guidance document for managing respiratory outbreaks to all long-term care facilities in California, with a reminder that they are required to report clusters of respiratory illness to their local health department and local Licensing and Certification district offices (22 California Code of Regulations § 72539 and 72541). Local health departments collect basic information regarding the timing and duration of outbreaks, any respiratory illness-associated hospitalizations or deaths, and numbers of residents and staff who received influenza vaccination or antiviral medications. Local health departments forward summary data to CDHS. CDHS encourages Local health departments to collect specimens for diagnostic testing at either local public health laboratories or VRDL.

- **Surveillance for human avian influenza.** Since the first reports of large-scale outbreaks of avian influenza A (H5N1) in domestic poultry in Asia in late 2003, CDHS has maintained enhanced surveillance for human cases of avian influenza using surveillance criteria recommended by CDC. CDHS has developed case screening guideline and form, an extended case report form for laboratory confirmed cases, a diagnostic testing algorithm, and an electronic database to track suspect cases, and makes the case report forms widely available through the VRDL California Influenza Surveillance Project website and other venues. CDHS also periodically distributes reminders and updates regarding the ongoing epidemic. CDHS reminds local health departments to report any cases that meet surveillance criteria to CDHS for consultation about case management and for help with expedited PCR testing for H5 at designated local public health laboratories or VRDL.

- **Surveillance for Vaccine Adverse Events.** CDHS monitors reports of vaccine adverse events and forwards copies to the National Vaccine Adverse Event Reporting System (VAERS). Periodically, CDHS analyzes the data to identify increased frequency and types of complaints.

- **DCDC Pandemic Influenza Work Group (PIWG):** The DCDC Pandemic Influenza Work Group (PIWG) consists of representatives of VRDL, Immunization Branch, and Infectious Diseases Branch. The team meets weekly throughout the influenza season to

review surveillance data, discuss the level of influenza activity, review individual cases and outbreaks, review vaccine supply distribution and allocation, work on communication activities, coordinate efforts with OPA, and assign tasks when action is needed.

Laboratory Surveillance

- **Sentinel Laboratories.** Each week, CDHS collects data on the number of laboratory-confirmed influenza cases and other respiratory virus detections and isolations from 19 laboratories. Participants include hospital, academic, private, and public health organizations with laboratories located throughout California, including Kaiser Permanente Northern California Regional Laboratory and Kaiser Permanente Southern California Regional Laboratory. Most of these laboratories have contributed data to the California Influenza Surveillance Project since 1998.

- **Respiratory Laboratory Network.** This network consists of 22 local public health laboratories, 20 of which offer enhanced diagnostic testing with the "R-mix" shell viral assay, which detects several respiratory pathogens, including influenza A and B viruses, respiratory syncytial virus, parainfluenza virus, and adenovirus. All 22 laboratories offer PCR testing for influenza A and B.

- **CDHS Viral & Rickettsial Disease Laboratory (VRDL).** VRDL serves as a statewide reference laboratory that offers diagnostic testing for influenza and a broad array of other respiratory pathogens using isolation, PCR, and serologic testing. VRDL assists with diagnostic testing in a variety of settings, including institutional or community respiratory outbreaks, individual cases of severe respiratory illness, cases that meet surveillance criteria for novel avian influenza, and isolation, subtyping, and strain characterization of viruses from cases of influenza-like illnesses submitted by sentinel providers. VRDL provides diagnostic testing without charge.

Chapter 3.

LABORATORY TESTING CAPACITY

This chapter addresses laboratory testing capacity. Epidemiologic investigation is covered separately in Chapter 2: Pandemic Influenza Surveillance and Epidemiology.

INTRODUCTION

Because influenza viruses are constantly changing, strong laboratory-based surveillance will be critical through all stages of the pandemic to monitor disease activity and changes in virus strain. Timely identification of circulating or novel virus strains is equally important for pandemic detection and vaccine preparation. During the earliest stages of the pandemic, public health and hospital laboratories are likely to receive a large number of specimens for testing. Planning for laboratory surge capacity and the availability of diagnostic reagents is essential for timely and effective testing. Once a pandemic is underway and the virus is widespread, laboratory confirmation for each case will not be necessary and testing priorities will likely focus on a subset of cases (e.g., severely ill cases, clusters of cases, or cases refractory to antiviral treatment).

OBJECTIVES

The objectives of the California Department of Health Services (CDHS) pandemic influenza activities for laboratory testing capacity are to:

- Characterize and monitor interpandemic influenza activity year-round, with continuous surveillance for the appearance of novel influenza strains;
- Perform enhanced surveillance for other non-influenza, viral respiratory pathogens year-round (e.g., respiratory syncytial virus, parainfluenza virus, and adenovirus);
- Once a novel virus has been detected in California, monitor the level of novel influenza virus activity statewide, including antiviral resistance patterns;
- Support special epidemiologic and clinical studies needed to evaluate phase-specific clinical interventions and containment measures;

- Assist with the clinical management of individual patients by performing special studies, including distinguishing infections caused by influenza from infections caused by other respiratory viruses; and

- Support individual case decisions surrounding isolation and quarantine.

ASSUMPTIONS AND PLANNING PRINCIPLES

- Because many respiratory agents can mimic the signs and symptoms of influenza, a comprehensive laboratory program that offers diagnostic testing for multiple respiratory agents is critical to monitoring for the introduction of a novel virus in California

- CDHS Viral and Rickettsial Disease Laboratory (VRDL) will provide the necessary leadership and guidance to local public health laboratories.

- Building strong, statewide laboratory-based surveillance in the interpandemic phase, including strengthening of partnerships between VRDL and local public health, private, and commercial laboratories will enhance the ability to monitor for disease activity and ultimately strengthen control measures.

- During the earliest stages of a pandemic, public health, hospital, and clinical laboratories will receive a large and potentially overwhelming volume of samples.

- During a pandemic, laboratory surveillance data, such as the confirmed presence or absence of a novel influenza virus in a given geographic area, will guide implementation of non-pharmaceutical containment measures (e.g., travel restrictions, closure of schools, and cancellation of public gatherings).

- During a pandemic, laboratory data identifying the emergence of new strains of novel virus will guide the implementation of vaccination strategies;

- During a pandemic, laboratory data identifying the presence or absence of antiviral drug resistance will guide the use of antiviral prophylaxis and treatment strategies.

- Once a pandemic is underway and human-to-human transmission is established, supplies of rapid antigen tests and reagents for immunofluorescence assays and polymerase chain reaction will likely be depleted. At this time, laboratory testing may be reserved for unusual or severe cases, special studies, or other specialized situations.

CDHS Pandemic Response Action Steps

WHO PHASE 1 AND PHASE 2

Interpandemic period: No novel influenza subtypes have been detected in humans, but a novel subtype that has caused human infection may be present or circulating in animals.

CDHS VRDL will:

- Develop and maintain laboratory testing algorithms, protocols, and strategies for use by CDHS, local public health laboratories, and the California Respiratory Laboratory Network to perform interpandemic influenza surveillance and to detect the emergence of novel influenza strains; these protocols will include standard diagnostic tests (e.g., virus isolation, direct antigen testing by rapid antigen tests and polymerase chain reaction, and serologic testing) and support the role of the public health laboratory in diagnosing interpandemic influenza under routine circumstances and in outbreak situations;

- In coordination with the local public health laboratories, develop and distribute recommended laboratory diagnostic guidelines for interpandemic influenza to all clinical settings (e.g., clinician offices, clinical laboratories, and local public health laboratory and disease control staff), including the role of commercial rapid antigen test kits in routine and outbreak situations and guidance on how to obtain further testing at CDHS and local public health laboratories, including specimen collection and transport protocols;

- Implement state-of-the art diagnostic testing algorithms for detecting and characterizing influenza, including testing for subtyping, strain-typing, immunity, and resistance;

- Transfer new technologies for influenza rapid testing (e.g., polymerase chain reaction and subtyping), to interested local public health laboratories; local public health laboratories receiving this technology will participate in proficiency testing;

- With local public health laboratories, develop laboratory capacity (personnel, supplies, reagents, and training) to perform year-round laboratory-based surveillance during the interpandemic period;

- With the California Association of Public Health Laboratory Directors, develop an inventory of current laboratory capacity in California, identify gaps in coverage, and recommend strategies to fill capacity gaps;

- With California Association of Public Health Laboratory Directors, estimate future laboratory capacity requirements under various pandemic scenarios and identify strategies for enhancing future capacity; and

- With local public health laboratories and the CDC, develop a policy for storing and sharing selected isolates and specimens to support special clinical and epidemiologic studies and maintain an inventory of current storage capacities.

WHO PHASE 3 AND PHASE 4

Pandemic Alert Period: Human infection with no or very limited human-to-human transmission

CDHS VRDL will:

- In collaboration with local public health laboratories,

    - encourage healthcare providers and clinical laboratories to submit specimens from suspected cases of human infection with novel influenza to a local or state public health laboratory for viral testing;

    - develop and distribute guidelines to hospitals, healthcare providers and clinical laboratories describing how to request testing for novel influenza virus; and

    - develop and distribute protocols to ensure that clinical laboratories notify their local public health laboratory of requests for testing for novel influenza virus;

- Develop guidelines for specimen collection, handling, and shipping, and post them on the VRDL-Flu website (www.dhs.ca.gov/ps/dcdc/VRDL/html/FLU/fluintro.htm);

- Adapt and distribute laboratory biosafety guidelines for handling and processing specimens or isolates of influenza A (H5N1) strains and post them on the VRDL-Flu website (www.dhs.ca.gov/ps/dcdc/VRDL/html/FLU/fluintro.htm);

- Develop and activate enhanced laboratory testing protocols in support of, and in coordination with, enhanced human surveillance protocols. VRDL will develop the capacity for subtype testing for influenza A (e.g., H5, H7) at either the local or state levels, as well as testing to identify other respiratory pathogens that present as influenza-

like illnesses, and coordinate transport to CDC any influenza A virus that cannot be subtyped;

- Provide detailed guidance to local public health laboratories on alternative diagnostic testing options, including rapid antigen detection, immunofluorescence assays, and polymerase chain reaction, including required biosafety levels;

- Develop contingency plans for possible nationwide supply and reagent shortages, including inventorying its own supplies and equipment and determining trigger points for ordering surge supplies; VRDL will set priorities in preparing reagents for identifying the novel virus strain, in preparation for pandemic Phase 5 and Phase 6, and will distribute California- or CDC-prepared reagents and primers to local public health laboratories that are enrolled in California's Response Laboratory Network, as available;

- Develop appropriate personnel capacity (including training) to support enhanced laboratory surveillance for influenza at the state and local levels. VRDL will internally evaluate the need for additional personnel surge capacity, including re-certification of non-traditional labor pool and redirection and hiring of additional laboratory employees;

- Develop contingency plans to ensure adequate laboratory capacity for diagnostic testing of bacterial agents and other pathogens associated with infections secondary to influenza; and

- Institute surveillance for influenza-like illness among CDHS laboratory personnel working with novel influenza viruses and develop protocols for clinical assessment and management of exposed laboratory personnel (both symptomatic and asymptomatic).

In addition, CDHS will ensure that at least one "BioSafety Level-3 enhanced laboratory" exists within its laboratory facilities.

WHO PHASE 5

Pandemic Alert Period With Substantial Pandemic Risk: Larger clusters but still limited human-to-human transmission; sustained community transmission is possible.

CDHS VRDL will:

- Review and revise enhanced laboratory diagnostic protocols for influenza and other respiratory pathogens that may mimic influenza and distribute them to local public health laboratories;

- Develop state and local contingencies and protocols for redirecting resources to influenza testing and for rationing influenza testing;

- Review and revise technical guidance and provide training to local public health laboratorians, as needed;

- Delineate the resources needed to maintain expanded critical laboratory testing capacity during a pandemic, including laboratory equipment and supplies, re-certification of non-traditional labor pool, and redirection and hiring of additional laboratory employees;

- Maintain expanded diagnostic testing, including antiviral resistance testing, neutralizing antibody assays to test for immunity to the novel virus, and egg-based or other alternative culture methods to isolate novel viruses that are difficult to grow by standard culture methods; and,

- Ensure capacity to perform or support special clinical and epidemiologic studies.

WHO PHASE 6

Pandemic Period: Increased and sustained transmission in the general population.

CDHS VRDL will:

- Review and enhance laboratory diagnostic capacity for novel virus, with particular attention to rationing laboratory testing, as needed; and

- Continue other Phase 5 activities as appropriate.

Chapter 4.

HEALTHCARE PLANNING

INTRODUCTION

This chapter addresses the role of the California Department of Health Services (CDHS) in supporting the coordination of optimal response by, and adequate maintenance of, the state's healthcare delivery system during a pandemic influenza emergency.

California's healthcare system consists of private and public healthcare providers. Oversight and regulation of, and emergency planning for, the healthcare system are shared between multiple divisions within CDHS, primarily the Licensing and Certification Division, as well as other state agencies, including the Emergency Medical Services Authority (EMSA) and the Office of Statewide Health Planning and Development.

The increased demand for healthcare services during an influenza pandemic will challenge existing healthcare resources in California to a level not previously experienced. The "over-capacity" protocols in place at most hospitals are designed to accommodate an increased number of patients over a short period. A pandemic will require a health response sustained for months or years. Planning for this kind of sustained response presents a unique challenge to hospitals, healthcare institutions (i.e., long-term care facilities, skilled nursing facilities), and other healthcare providers and will require collaboration and integration between all healthcare partners. CDHS must work collaboratively with local health departments, local emergency medical services, healthcare facilities, medical providers, state agencies, and others to prepare to meet this demand.

BACKGROUND

CDHS pandemic planning efforts build upon local, regional, and state planning efforts. Under the National Bioterrorism Hospital Preparedness Program funded by the Health Resources and Services Administration, local planning groups have developed plans to respond to a sudden and marked increased demand for patient care related to an emergency event. Healthcare surge capacity is defined as "the ability to evaluate and care for a markedly increased volume of patients that exceeds normal operating capacity." [2]

[2] Medical Surge Capacity and Capability. The CNA Corporation, 2004.

As required by the Health Resources and Services Administration cooperative agreement, local planning groups include representatives of healthcare partners including local health departments, hospitals, clinics, poison control centers, emergency medical services, state-run institutions, and other stakeholders. These local planning groups must meet benchmarks to ensure sufficient patient care surge capacity in an emergency of 500 cases per million (1:2000) pediatric and adult patients above the current daily-staffed bed capacity. This Health Resources and Services Administration benchmark is a *starting point* for healthcare planning during a pandemic that necessitates significant increased capacity for an extended time and affecting the entire state.

CDHS has projected the impact upon California's medical and health system during an influenza pandemic using CDC's FluSurge 2.0 software. The projections assumed an attack of eight weeks duration during which 25 percent of the population would become ill. The projections also assumed that the severity of the epidemic would be a moderate level pandemic, intermediate level (i.e., the 1967 pandemic) and severe level (i.e., the 1918 pandemic.) Based upon historic data provided by CDC, in such an epidemic 4.4 percent of affected persons would be expected to be admitted to hospitals and 26.7 percent of these would be expected to die. Based on this death rate, the CDHS projections assumed that 35 percent of admitted patients would require critical care (ICU or monitored beds), and 30 percent would require the use of ventilators. The California Department of Finance 2006 population data were used for age-group inputs. The results of these projections include:

- Hospital capacity to treat influenza patients would begin to exceed the state's hospital surge bed capacity (as of May 2006) in week 2 of the pandemic and in week 5 the surge bed capacity would be exceeded by 319 percent.

- In week 5, total need for critical care beds would exceed surge capacity by 1212 percent and the need for ventilators would exceed the number of available full-service ventilators by 1350 percent.

- Deaths are estimated to be 21,064 during an eight-week period in the first wave of the pandemic.

The magnitude of the shortfall for hospital needs could be significantly less in an epidemic with a lower attack rate or lower disease severity (requiring fewer hospital admissions). Subsequent attack waves in the same epidemic could also be expected to require fewer hospital resources. However, even in very mild scenarios the capacity of hospitals is likely to be significantly exceeded.

OBJECTIVES

The objectives of the CDHS pandemic influenza activities for healthcare planning are to:

- Maintain to the extent possible the provision of healthcare services sufficient to meet the needs of Californians during an influenza pandemic;
- Maximize California's ability to respond to the healthcare needs resulting from an influenza pandemic through effective planning at the state level; and
- Collaborate with local health departments and healthcare providers to anticipate the healthcare surge capacity demands of an influenza pandemic.

ASSUMPTIONS

- Local health departments are the lead agencies for pandemic planning at the local level.
- Local health departments should coordinate with and ensure active participation from hospitals, local emergency medical services agencies, community clinics or health centers, private practice physicians, home-based care, long-term care facilities, and other healthcare partners.
- Local pandemic healthcare planning will build on local surge planning efforts undertaken through the Health Resources and Services Administration's cooperative agreement.
- The increased demand for services and response during an influenza pandemic will severely challenge the capacity of CDHS, local health departments, and medical and health providers including hospitals, emergency medical services, community clinics or health centers, private practice physicians, home-based care, long-term care facilities, pharmacies, and other healthcare partners throughout California and the nation.
- Patient care surge capacity needed during a pandemic will exceed hospital capacity and must be a community responsibility
- Healthcare providers must be prepared to manage the surge of pandemic influenza patients presenting for care based on general predictions from the U.S. Department of Health and Human Services and based on current data of influenza outbreaks.
    - The clinical disease attack rate is estimated to be 25 to 35 percent of the population.
    - About 50 percent of ill persons will seek outpatient medical care.
    - Hospitalization will be required for a large number of those severely ill.

- About 20 percent of working adults will be affected.
- Illness rates will be the highest among school-aged children (approximately 40 percent) and decline with age.
- An average of two secondary infections will occur per infected person.
- The pandemic may last up to 18 months and several waves are likely.

- After the pandemic, the novel virus is likely to continue circulating and to contribute to seasonal influenza.

- Because of the widespread impact of an influenza pandemic, capacity for medical mutual aid may be limited or unavailable within California, between states, and between California and Baja California.

- Local healthcare surge capacity planning must include cooperative strategies that integrate the spectrum of healthcare providers, including hospitals, emergency medical services, community clinics or health centers, private practice physicians, home-based care, long-term care facilities, and other healthcare partners.

- Supplies, equipment, and pharmaceuticals will be in short supply during an influenza pandemic. Local healthcare surge capacity and pandemic influenza planning must prepare for shortages and should consider stockpiling of critical supplies, equipment, and pharmaceuticals.

- Effective outpatient management may reduce the demand for inpatient care. Home-based treatment provided by families, and supported by primary care practitioners, public and home health agencies, or other health professionals will be an essential resource during a pandemic.

- Under a Governor's proclamation of emergency for California or an area of the state, CDHS can modify healthcare standards to help meet the immediate needs for patient care related to the influenza pandemic.

- Traditional standards of care may need to be altered to maximize healthcare resources and benefits. "Sufficiency of care," or medical care that may not be of the same quality as that delivered under non-emergency conditions but that is sufficient for need[3], may be the standard of care during an influenza pandemic.

[3] Surge Hospitals: Providing Safe Care in Emergencies. Joint Commission on Accreditation of Healthcare Organization, 2006.

- Hospitals should anticipate and strive to maximize their healthcare surge capacity. CDHS will grant permission to exceed licensed capacity under appropriate circumstances. However, when hospital capacity is exceeded, alternate care sites will be needed to augment acute care facilities. Hospitals will be used for patients needing higher levels of care.

- Local health departments have responsibility for planning and coordination of alternate care sites at the local level.

- Hospitals and other healthcare providers will experience staffing shortages throughout the pandemic and into the recovery period.

- Volunteers, retired healthcare professionals, and trained, unlicensed personnel may be used under specific emergency conditions to augment patient care in a variety of healthcare settings.

- Healthcare facilities, medical examiners, county morgues, mortuaries, and funeral homes must plan for surge capacity in mass fatality management during an influenza pandemic.

- Coordination of pandemic healthcare planning should include neighboring states and countries (i.e., California-Baja California region).

COMPONENTS OF PLANNING

The planning activities described in this section are complex and extend across pandemic phases.

Pandemic healthcare planning is divided into the components listed below.

- Facilities include both traditional and alternate care sites (e.g., settings traditionally used for outpatient care or settings that now provide lower levels of healthcare, temporary structures, reopened health facilities, school gymnasiums, armories, hotels and motels, convention centers). Evaluation of or planning for sites should include physical structures, critical infrastructures (such as plant operations and transportation), and the incident command systems (i.e. Hospital Incident Command System) to manage them.

- Equipment and supplies include equipment needed for patient care (e.g., beds, ventilators, heating-ventilating-air conditioning) and medical supplies, such as pharmaceuticals and consumable medical equipment (e.g., intravenous sets, personal care supplies for patients, and personal protective equipment for staff).

- Personnel planning includes maximizing existing staffing resources and expanding staffing resources with alternative practitioners, volunteers, and newly recruited personnel.

- Statutes, regulations, and policies established by the state and federal governments to govern healthcare provision and practice may be modified or waived during an emergency.

- Protocols, procedures, and guidelines needed to manage patients during a pandemic in various settings include staffing plans, transfer procedures, infection control guidelines, clinical pathways and protocols for treating influenza patients, triage before entry into the healthcare facility, rationing scarce commodities (i.e., ventilators), and operating alternate care sites.

- Training for healthcare providers, families, volunteers, and newly recruited staff.

- Coordination and communication within facilities, the local health departments, communities, regions, and statewide.

CDHS Pandemic Response Action Steps

WHO PHASE 1 AND PHASE 2

Interpandemic Period: No novel influenza subtypes have been detected in humans, but a novel subtype that has caused human infection may be present or circulating in animals.

Facilities

CDHS will:

- Develop protocols, procedures, and guidelines needed to manage patients during a pandemic in various settings include staffing plans, transfer procedures, infection control guidelines, clinical pathways and protocols for treating influenza patients, triage before entry into the healthcare facility, rationing scarce commodities such as ventilators, and operating alternate care sites;

- Draft model emergency orders to maximize healthcare surge capacity;

- Review, update, and if necessary, revise or expand regulatory or statutory authority to ensure that hospitals and other healthcare facilities complete emergency preparedness planning related to catastrophic events such as pandemic influenza;

- Explore legal authority and regulatory changes to require healthcare facility emergency planning as a condition of licensure, including:

- requiring hospitals to develop specific triggers (or thresholds) for implementing healthcare surge capacity plans, augmenting and retaining staff, obtaining critical supplies and using alternate space or temporary shelters to manage increased demands; and

- requiring long-term care facilities to develop protocols and plans to manage patients with higher acuities through emergency admissions or existing residents who are unable to be transferred to acute care hospitals due to lack of capacity;

- Review local healthcare surge capacity plans and recommend the revision of the plans to promote consistency across the regions and the State; and

- In conjunction with EMSA and the Office of Statewide Healthcare Planning and Development, assess and enhance existing hospital bed reporting systems for statewide reporting of healthcare surge capacity.

Equipment and Supplies

CDHS will:

- Verify that local healthcare surge capacity plans include a system to maintain a current inventory of essential healthcare items such as cots, ventilators, personal protective equipment, and pharmaceuticals; and

- Collaborate with local health departments to update inventories of essential healthcare items and supplies throughout the state.

Personnel

CDHS, in conjunction with the Department of Consumer Affairs, EMSA, and other professional licensing entities, will:

- Review existing legal authority related to the use of healthcare volunteers;

- Determine the viability of temporarily expanding the scope of practice for specific licensed or certified healthcare professionals during influenza pandemic, including: physician assistants, paramedics, emergency medical technicians, nurses, dentists, veterinarians, podiatrists, pharmacists, respiratory care practitioners and psychiatric technicians;

- Determine mechanisms to permit unlicensed healthcare workers, such as nursing and medical students, and volunteers to perform specific patient care procedures, including vaccinations and dispensing prophylactic medication during an influenza pandemic;

- Ensure that local healthcare surge capacity plans include surge strategies to meet staffing needs;

- Develop and maintain a system to identify the skills of CDHS staff with healthcare skills for potential deployment;

- Work with Department of Social Services to explore potential use of Volunteer Emergency Services Team members; and

- In collaboration with medical professional societies, EMSA and others, develop principles and approaches to alternate standards of care in mass casualty situations, including suggested triggers, liability protections, communications, and other critical issues.

CDHS, in conjunction with EMSA, the California Service Corps, local health departments, and others, will:

- Encourage the development of Medical Reserve Corps in all counties and assist in developing guidelines for their use and deployment; and

- Participate in developing an automated Emergency System for the Advanced Registration of Volunteer Health Professionals in California.

Communications (See also Chapter 10: Pandemic Influenza Risk Communication Plan)

CDHS will:

- Ensure communications mechanisms, such as the California Health Alert Network (CAHAN) and the CDHS website, disseminate pandemic influenza-related information to local health departments and healthcare providers, including hospital-based infection control practitioners; and

- Develop a system for regular reporting of bed capacity, staffing, and critical supply inventories throughout the pandemic.

Mass Fatalities

CDHS will verify that local healthcare surge capacity plans address the management of mass fatalities related to an influenza pandemic.

WHO PHASE 3 AND PHASE 4

Pandemic Alert Period: Human infection with no or very limited human-to-human transmission.

Facilities

CDHS, in consultation with medical professional organizations and other stakeholders, will:

- Develop initial recommendations for patient triage including:
    - prioritizing limited resources within the healthcare system;
    - assigning patients to specific treatment settings (e.g., medical center, clinic, long-term care, home care, alternate care sites); and
    - accelerating discharge of patients from one level of care to another;
- Issue recommendations for the use of alternate care sites, including:
    - activation criteria;
    - minimum requirements for size, power, air and heat, equipment, supplies and security;
    - staffing;
    - infection control;
    - liability;
    - memoranda of understanding or other agreements for procuring and distributing resources and supplies;
    - best practices from other jurisdictions and states; and
    - address barriers to the use of alternate care sites, including developing model emergency orders;

- In conjunction with the California Department of Food and Agriculture, assess the potential use of local fairgrounds for pandemic-related activities; and

- In conjunction with EMSA, develop and test a statewide hospital capacity monitoring system to assess the healthcare surge capacity of acute care hospitals, including state-owned and managed facilities.

Equipment and Supplies

CDHS will:

- Collaborate with local health departments to develop a list of key pandemic supplies, inventory these supplies, and review the feasibility of stockpiling additional supplies; and

- Assess the potential to create regional stockpiles of essential equipment and supplies and develop distribution plans for these materials.

Personnel

CDHS will:

- Disseminate work products from Phase 1 and Phase 2 related to professional scope of practice requirements;

- Advise local health departments and healthcare providers regarding draft emergency orders for modifying scope of practice requirements;

- Exercise local pandemic plans in collaboration with healthcare facilities and other providers, the Governor's Office of Emergency Services, the Governor's Office of Homeland Security, local health departments, Regional Disaster Medical and Health Specialists, Medical and Health Operational Area Coordinators, healthcare volunteers, and expanded practice professionals;

- Collaborate with EMSA to develop call-up, activation, and deployment procedures and protocols for healthcare professionals who are registered in an Emergency System for Advanced Registration of Volunteer Healthcare Personnel system; and

- Implement procedures for identifying CDHS healthcare personnel.

Communication **(See also Chapter 10: Pandemic Influenza Risk Communication Plan)**

CDHS will:

- Convene regular conference calls with local health departments and other partners to discuss pandemic progress and scope, and refine healthcare planning guidance; and

- Use the CDHS website, CAHAN, and other communication mechanisms to transmit pandemic related information for the public, healthcare delivery organizations, their employees, volunteer workers, and local health departments.

Mass Fatalities

CDHS, working with the Governor's Office of Emergency Services, the Department of Consumer Affairs, coroners/medical examiners, and others, will:

- Clarify jurisdictional authority and resolve issues concerning the large-scale management of mass fatalities related to an influenza pandemic;

- Develop model emergency orders to address mass fatality issues (i.e., mass body storage);

- Issue recommendations for the definition of a medical examiner or coroner's case based on the case definition of infection with the pandemic influenza virus; and

- Issue recommendations on mass fatality management for healthcare facilities.

WHO PHASE 5

Pandemic Alert Period With Substantial Pandemic Risk: Larger clusters but still limited human-to-human transmission; sustained community transmission is possible

Facilities

CDHS will:

- Continue actions initiated in previous phases; and

- Monitor capacity reports from hospitals through established SEMS channels and manage resource requests.

Equipment and Supplies

CDHS will:

- Continue and complete actions initiated in previous phases; and
- Collaborate with local health departments to ensure the readiness of stockpiled supplies and distribution systems.

Personnel

CDHS will:

- Continue and complete actions initiated in previous phases;
- Train CDHS healthcare personnel for pandemic response; and
- Test deployment protocols for CDHS healthcare personnel.

Communication

CDHS will:

- In conjunction with EMSA, activate the Joint Emergency Operations Center (JEOC) to ensure readiness for surge response, communicating the status of the pandemic, and the coordinating healthcare personnel, facilities, equipment, and supplies; and
- Continue actions initiated in previous phases.

WHO PHASE 6

Pandemic Period: Increased and sustained transmission in the general population.

CDHS will:

- Activate emergency plans for personnel, supplies, alternate care sites, and mass fatality management after the Governor's declaration of a state of emergency;
- In conjunction with EMSA, the Department of Consumer Affairs, and the Governor's Office of Emergency Services, implement emergency orders and protocols related to

healthcare provider's licensure, scope of practice, staffing requirements, patient capacity, alternate care sites, healthcare volunteers, and the management of mass fatalities;

- Through the JEOC, monitor and coordinate the following activities in response to local and regional resource requests transmitted through the Governor's Office of Emergency Services:
    - use and supply of additional personnel**;**
    - use and expansion of healthcare facilities, including alternate care sites and fatality management resources;
    - use and supply of equipment, supplies, and pharmaceuticals; and
    - use and supply of healthcare transportation resources; and
- Monitor hospital care, alternate care sites, long term care facilities and alternate standards/sufficiency of care as necessary to provide care deemed appropriate and reasonable to provide care for most people.

WHO Postpandemic Period

Pandemic influenza is anticipated to arrive in two to three waves over the course of several years, with a trough between the waves. These periods of substantial decreases in new cases offer opportunities for recovery and a chance to regroup, learn, and prepare for the next wave.

CDHS will:

- Identify and share best practices related to information dissemination, clinical management, infection control, coordination of patient management, and other issues;
- Compile reports of shortages to validate planning assumptions regarding critical supplies and resources;
- Compile morbidity and mortality reports by treatment setting to understand how care may best be provided;
- Evaluate the use of volunteers, expanded scope, alternate care sites, and other practices used to expand/enhance surge capacity during the pandemic;
- Evaluate morbidity among hospital staff and the resulting impact on the provision of care;
- Adjust guidance for the use of personnel, supplies, and facilities; and

- Review and update guidance and recommendations issued during the previous phases.

Appendix B.

PLANNING CONSIDERATIONS FOR HEALTHCARE FACILITIES

This appendix is intended to assist healthcare facilities to prepare for catastrophic events such as pandemic influenza. These facilities should review the activities outlined below and consider them when developing and evaluating their surge plans.

ASSUMPTIONS

- Healthcare planning for pandemic influenza builds on efforts initiated under the National Bioterrorism Hospital Preparedness Program funded by the Health Resources and Services Administration.

- The increased demand for healthcare during an influenza pandemic will severely challenge the capacity of the healthcare system in California.

- Hospitals will be expected to maximize surge capacity. However, when hospital capacity is exceeded, alternate care sites will be needed to expand the availability of acute care. Hospitals should be used for patients requiring the highest level of care.

- The increased demand for healthcare associated with pandemic influenza cannot be managed by healthcare facilities alone. An effective pandemic response must include cooperative strategies that use a variety of healthcare providers, including hospitals, clinics, long-term care facilities, private practice physicians, and home health providers.

- Effective outpatient management may reduce the demand for inpatient care. Expanded clinic services and home health care provided by families who are supported by primary care practitioners, public and home health agencies, or other health professionals will be essential resources during a pandemic.

- Hospitals and other healthcare providers will experience staffing shortages throughout the pandemic and into the subsequent recovery period. Under specific emergency conditions, volunteers, retired healthcare professionals, and trained unlicensed personnel may be used to provide patient care in a variety of healthcare settings.

- During the interpandemic and pandemic alert periods, healthcare providers and facilities play an essential role in surveillance for suspected cases of infection with novel strains of influenza virus and should be alert for such cases.

- Hospitals and other healthcare providers should be prepared to report data to local health departments including beds, staffing, and critical supply inventories.

- Current resources for mass fatality care at all levels, including healthcare facilities, county morgues, and mortuaries, may be inadequate to meet the need during an influenza pandemic.

- To maximize healthcare resources and benefits, traditional standards of care may need to be altered. "Sufficiency of care," or medical care that may be of the same quality as that delivered under non-emergency conditions, but that is sufficient for patient need[4] may be the standard of care during an influenza pandemic.

- The pandemic could last for months or years. Local pandemic planning groups and healthcare facilities should meet regularly to assess the effectiveness of their pandemic response and modify efforts as indicated.

Decision-Making and Coordination

Healthcare facilities should:

- Convene a surge planning committee to develop a facility plan for responding to catastrophic events such as pandemic influenza, including:

    - incident management and communication protocols for continuity of hospital operations and patient care services;

    - specific pandemic influenza planning strategies that incorporate current state and federal guidance; and

    - triggers for activating the plan;

- Include on the facility planning committee a local health department representative as an ex-officio member;

- Participate in local pandemic planning groups that include representatives from the local health departments, the Medical Health Operational Area Coordinator, the local emergency medical services agency, law enforcement, county medical societies, and

[4] Surge Hospitals: Providing Safe Care in Emergencies. Joint Commission on Accreditation of Healthcare Organization, 2006.

other healthcare facilities, including clinics, long-term care facilities, and home health agencies;

- Discuss with community partners patient management strategies to preserve hospital capacity for patients requiring higher levels of care including:
    - community education and communication (see Chapter 10: Pandemic Influenza Risk Communication Plan);
    - public health outreach to promote self care (see Chapter 10: Pandemic Influenza Risk Communication Plan);
    - expanded clinic use;
    - use of home health agencies and in-home health services to facilitate outpatient management;
    - collaboration with long-term care facilities to minimize hospital admissions of nursing home patients and to maximize long-term care resources for managing stable, non-contagious hospital patients;
    - collaboration among healthcare and community leaders on plans to operate, equip, staff, and transport patients to alternate care sites (e.g., shuttered hospitals, outpatient facilities, veterinary hospitals, non-medical facilities) for triage or management;
    - memoranda of understanding or other agreements for procuring and distributing resources and supplies within the jurisdiction;
    - vaccine and antiviral dispensing to and use by designated target groups (see Chapter 7: Pandemic Influenza Vaccine Program and Chapter 8: Pandemic Influenza Antiviral Drug Program); and
    - liaison with local, regional, and state officials; volunteer groups; county medical societies; and community-based organizations to plan a surge response, identify potential healthcare volunteers, and exercise local, regional, and state plans.

Legal and Ethical Considerations

The healthcare facility's surge planning committee should include representatives from the facility's ethics or human subjects committee, infection control practitioners, emergency management committee, staffing director, administration, and physician leadership. The surge planning committee should develop policies on:

- Requesting and obtaining emergency waivers of regulatory requirements (e.g., Health Insurance Portability and Accountability Act, Emergency Medical Treatment and Active Labor Act, staffing ratios, scope of practice restrictions);

- Enforcing isolation and quarantine protocols;

- Allocating limited resources, including diagnostics, therapeutic interventions, personnel and beds, and issues related to the "sufficiency of care;"

- Establishing temporary patient care areas and morgue space within the facility;

- Using volunteer and newly recruited personnel;

- Accelerating discharge to alternate care sites or home-based care;

- Deferring elective procedures; and

- Interfacing with home health and long-term care facilities.

Facilities

Healthcare facilities should:

- Review and revise high patient census protocols to prepare for an influenza pandemic;

- Review and revise high patient census protocols to prepare for increased demands for isolation capacity;

- Develop plans for use of overflow space to triage, transfer, discharge, and treat patients, including using suspended beds, converting outpatient space for inpatient use, and using non-patient areas for patient care, including obtaining permission from CDHS to use these spaces in an emergency; and

- Identify strategies such as education, phone advice, and treatment algorithms to minimize emergency department visits and admissions.

Communications (See also Chapter 10: Pandemic Influenza Risk Communication Plan)

Healthcare facilities should work with public health officials, other government officials, neighboring healthcare facilities, private physicians and providers, the public, and the press to ensure rapid and ongoing information sharing during an influenza pandemic.

External Communications

Healthcare facilities should:

- Assign responsibility (persons or a team) for managing external communications about pandemic influenza;
- Develop contacts, working relationships, and communication plans with local media representatives (e.g., newspaper, radio, television);
- Coordinate communications with local and state health and government officials and other healthcare facilities;
- In collaboration with local health department officials, develop pre-scripted messages and communication templates (e.g., press releases) to address pandemic influenza issues; and
- Determine how to respond to or refer public inquiries.

Internal Communications

- Healthcare facilities should develop plans to keep personnel, patients, volunteers, and visitors informed of the impact of the pandemic on the facility and the community.

Personnel

Healthcare facilities should:

- Identify critical staff roles, including healthcare workers, medical staff members, housekeepers, dietary and laundry workers, plant operations, security, chaplains and mental health staff, and management, and develop plans to cover these critical roles;
- Develop pandemic-specific triggers for implementing critical staffing procedures;
- Ensure medical staff participation in the planning for personnel mobilization and surge capacity;
- Develop work force preservation protocols to minimize absenteeism, which may include:
    - rosters of staff teams that allow for rotation and rest over the duration of the pandemic;
    - employee counseling services to manage grief, exhaustion, anger, fear, physical and mental care of self and loved ones, and resolution of ethical dilemmas;

- support of healthcare workers in need for rest and recuperation;
- housing and food for healthcare personnel who must remain on-site for prolonged periods; and
- support for staff with child-care or eldercare responsibilities (e.g., day-care services);

- Prepare to manage volunteer personnel, including:
  - granting emergency privileges;
  - establishing competency, conducting criminal record clearance, and monitoring performance;
  - assigning temporary personnel;
  - using retired and volunteer healthcare workers for some patient care roles;
  - using community volunteers for non-clinical roles such as transporting specimens, registration, and supply handling; and
  - training volunteers;
- Coordinate staffing plans with the community pandemic influenza planning group to avoid competing for personnel resources;
- Develop just-in-time training and orientation for temporary and volunteer staff; and
- Develop model memoranda of understanding for using temporary personnel.

Supplies

Healthcare facilities should:

- Inventory critical supplies;
- Determine usage levels and consider stockpiling critical supplies;
- Develop memoranda of understanding with vendors for procuring additional supplies including: masks, gloves, gowns, beds and cots, intravenous supplies, portable high efficiency particulate air filters (HEPA), and ventilators;

- Test systems for procuring and storing additional supplies and address stockpile rotation issues;

- Repair durable equipment not in full working order and shorten routine maintenance cycle;

- Coordinate plans with the local pandemic planning group to avoid competing for supplies; and

- In conjunction with CDHS and the local pandemic planning group, develop a community-wide plan for supplying and equipping alternate care sites.

Hospital Surveillance for Pandemic Influenza

Healthcare providers and healthcare facilities will play an essential role in pandemic influenza surveillance. To detect cases of novel virus infection, hospitals should:

- Conduct surveillance in emergency departments to detect increases in influenza-like illness during the early stages of the pandemic;

- Monitor employee absenteeism for increases that might indicate early cases of pandemic influenza;

- Track emergency department visits and hospital admissions and discharge of suspected or laboratory-confirmed pandemic influenza patients; this information will be needed to:

    - support local public health personnel in monitoring the progress and impact of the pandemic;

    - assess bed capacity and staffing needs; and

    - detect resurgence in pandemic influenza that might follow the first wave of cases;

- Report requested data to the local health departments and the Medical and Health Operational Area Coordinator (e.g., admissions, discharges, deaths, patient characteristics, such as age, underlying disease and secondary complication; illness in healthcare personnel), using the system developed or recommended by CDHS and local health departments;

- Conduct pre-event planning with local health departments on protocols for data collection and reporting during the pandemic;

- Establish criteria for distinguishing pandemic influenza from other respiratory illnesses;

- Provide education and exercises on disease identification, testing, and reporting;
- Consider participating in the CDHS Immunization Branch Sentinel Provider reporting program;
- Establish priorities for laboratory procedures, including processing specimens; and
- Assess communication systems to ensure receipt and dissemination of alerts and bulletins from local, regional, and state infection control partners.

Infection Control (See also Chapter 5: Infection Control in the Healthcare Setting)

Healthcare facilities should:

- Convene the infection control committee to review and revise infection control policies and plans relevant to the pandemic response, including:
    - establishing a system for conducting surveillance for pandemic influenza cases within the facility;
    - patient triage systems;
    - facility access and restriction of visitors;
    - non-pharmaceutical containment strategies;
    - respiratory hygiene;
    - isolation;
    - cohorting patients;
    - workforce issues, such as training, personal protective equipment, and guidelines for "fitness for duty" status; and
    - cleaning equipment and environments;
- Review and update staff training in infection control policies and procedures, including training for non-clinical hospital personnel such as housekeepers, admitting clerks, and other critical support staff;
- Require demonstration of staff proficiency in critical infection control techniques;

- Adopt "respiratory hygiene" programs in all patient and visitor waiting areas to include signs about respiratory etiquette, hand cleaning supplies, tissues, masks, and waste receptacles; consider requiring all coughing patients to don a mask;

- Inventory respiratory isolation capacity and assess the integrity of airborne infection isolation room systems; and

- Develop strategies for expanding respiratory isolation capacity and cohorting infectious patients.

Vaccine Program and Antiviral Program (See also Chapter 7: Pandemic Influenza Vaccine Program and Chapter 8: Pandemic Influenza Antiviral Drug Program)

Healthcare facilities should:

- Review the current healthcare worker and patient vaccination program for pneumonia and influenza;

- Develop internal policies and protocols to identify high-risk patients for vaccine or antiviral distribution, according to the CDHS-established priorities;

- Identify critical hospital personnel for vaccination and antiviral medication, according to the CDHS established priorities; and

- Collaborate with local health departments on distribution and dispensing plans for vaccine and antivirals.

Case Management and Treatment (See also Chapter 5: Infection Control in the Healthcare Setting)

Healthcare facilities should:

- Adopt treatment guidelines distributed by CDC and CDHS;

- Develop standard operating procedures to ensure rapid and consistent application of treatment guidelines and inpatient care protocols in conjunction with the medical staff;

- Train medical staff on treatment priorities, allocating limited resources, and "sufficiency of care" standard;

- Develop systems to rapidly disseminate and update guidance to clinical staff and to revise policies and standard operating procedures accordingly; and

- Develop and enforce policies and procedures for dealing with healthcare workers who become ill.

Mass Fatalities

Healthcare facilities should:

- Review current disaster plans for managing remains and handling morgue overflow;
- Develop plans to manage contaminated remains for days;
- Collaborate with local health department and coroner/medical examiner in mass fatality planning; and
- Consider memoranda of understanding for surge mortuary supplies (e.g., body bags, refrigerator trucks).

Education and Training

Healthcare facilities should:

- Develop an education and training plan that addresses the needs of staff, patients, family members, and visitors;
- Educate staff, at a minimum, on:
    - prevention and control of influenza including potential changes in current practices, policies, and procedures;
    - benefits of an annual influenza program;
    - implications of an influenza pandemic;
    - role of antivirals in preventing disease and reducing rates and severity of disease;
    - infection control strategies and personal protective equipment;
    - non-pharmaceutical containment measures (internal and community);
    - policies and procedures for the care of the pandemic influenza patient(s);
    - pandemic staffing contingency plans and managing employee illness;
    - reporting to the local health department; and

- cross-training and “just-in-time” training of staff to provide essential services;

- Prepare educational materials for patients, family members and visitors in language-specific and reading-level appropriate materials and develop a plan to distribute information and answer questions during the pandemic, using materials from CDC, CDHS, and local health departments; and

- Conduct periodic exercises to test and evaluate pandemic plans, policies, and procedures.

Chapter 5.

INFECTION CONTROL IN THE HEALTHCARE SETTING

INTRODUCTION

This chapter addresses infection control measures and practices in the healthcare setting and provides guidance to healthcare facilities on managing a pandemic influenza outbreak. This guidance is based on current knowledge of the routes of influenza transmission, the pathogenesis of the influenza virus, and the effects of influenza control measures used during past pandemics and interpandemic periods. The specific characteristics of a novel pandemic virus will remain unknown until the pandemic occurs. The California Department of Health Services (CDHS) will revise this document as needed to meet the changing dynamics of a pandemic.

The primary strategies for preventing pandemic influenza are the same as those for seasonal influenza: vaccination, early detection, treatment with effective antiviral medications, and the use of infection control measures to prevent transmission during patient care. However, when a pandemic begins, a vaccine will not be widely available and the supply of antiviral drugs may be limited. The ability to limit transmission in a healthcare setting will depend significantly on appropriate and thorough application of infection control measures.

Given the uncertainty about the characteristics of a pandemic virus strain, all aspects of preparedness planning for pandemic influenza must allow for flexibility and real-time decision-making as the situation unfolds. Healthcare facilities should be prepared to implement engineering and administrative controls and use of personal protective equipment to prevent all possible modes of transmission, including airborne. Preparedness includes having a respiratory protection program in place; pre-designating which employees might be required to wear respiratory protection; and ensuring that potential respirator users have been medically cleared, have selected a suitable respirator model through individual fit testing, and have been trained in respirator use. In addition, adequate supplies of respirators and other personal protective equipment must be onsite and plans in place to acquire additional equipment on short notice.

OBJECTIVES

CDHS objectives for infection control measures in the healthcare setting are to:

- Limit transmission from:
    - infected patients to non-infected healthcare staff;
    - infected patients to non-infected patients;
    - infected healthcare staff to non-infected patients;
    - infected healthcare staff to non-infected healthcare staff; and
    - infected visitors to non-infected patients or staff; and
- Provide infection control guidance to healthcare facilities on managing pandemic influenza outbreaks.

ASSUMPTIONS AND PLANNING PRINCIPLES

- Infection control needs will change as an influenza pandemic evolves from first identification of a novel influenza virus in one or more persons to when a pandemic, with efficient human-to-human transmission, actually occurs. CDHS will review data and scientific evidence, consult with local health officers, review national recommendations, and revise and update infection control guidance and recommendations as indicated.
- Susceptibility to the pandemic influenza virus will be universal before vaccination or recovery from infection.
- An average of two secondary infections will occur per infected person.
- After the pandemic, the novel virus is likely to continue circulating and to contribute to seasonal influenza.
- People may be asymptomatic while infectious and the incubation period may be as little as two days, as with seasonal influenza.
    - Viral shedding will occur one-half to one day before the onset of illness;

- Shedding will be the heaviest in the first two days after symptoms appear;

- Children are typically heavy viral shedders in the first few days of illness (one day before onset of illness and two days after); and

- The infectious period in adults is typically three to five days, in some children and the immunocompromised viral shedding may persist for several weeks. These estimates will be revised based on viral shedding studies available on pandemic strain.

- The modes of transmission of a novel influenza virus may vary from seasonal influenza outbreaks. Therefore, the California Division of Occupational Safety and Health (Cal/OSHA), in collaboration with the Occupational Safety and Health Standards Board, may develop workplace standards specific to the influenza pandemic, altering the recommendations in this chapter. Even if influenza transmission has not reached the pandemic phase, Cal/OSHA may develop the workplace standards if transmission presents a workplace hazard.

- Once the pandemic is underway and human-to-human transmission is established, infection control resources, including personal protective equipment, may be limited. Healthcare providers must be prepared to prioritize the use of personal protective equipment, allocate scarce resources, and manage the patient surge.

MODES OF INFLUENZA TRANSMISSION

Despite the annual prevalence of influenza, most information on the modes of influenza transmission from person-to-person is indirect and largely obtained through observations during outbreaks in healthcare facilities and other settings (e.g., cruise ships, airplanes, schools, and colleges). The amount of direct scientific information is limited. However, the observed epidemiologic pattern observed is generally consistent with spread through close contact (i.e., exposure to large droplets, direct contact, or near-range exposure to aerosols). There is little evidence of airborne transmission over long distances or prolonged periods, but the relative contributions and clinical importance of the different modes of influenza transmission are currently unknown.

For any novel influenza strain, the mode of transmission and recommendations for personal protection and isolation precautions (i.e., droplet, contact, airborne) must be determined at the time of the pandemic, based on the best available evidence at that time.

Droplet Transmission

Droplet transmission involves contact of the conjunctivae[5] and or mucous membranes of the nose or mouth of a susceptible person with large-particle droplets containing microorganisms generated from a person who has a clinical disease or who is a carrier of the microorganism. Droplets are generated from the source person primarily during coughing, sneezing, or talking and during the performance of certain medical procedures, such as suctioning and bronchoscopy. Transmission via large-particle droplets requires close contact between source and recipient because droplets do not remain suspended in the air and generally travel only short distances (about three feet) through the air. Because droplets do not remain suspended in the air, special air handling and ventilation are not required to prevent droplet transmission. Large droplets (particles up to 100 microns in size) are considered inhalable or "inspirable," even if they may not remain airborne for a long period; this fact supports the use of respiratory protection when a healthcare worker is within close contact of a coughing or sneezing patient.

Given epidemiologic patterns of disease transmission, large droplet transmission is probably a major route of influenza transmission. However, data confirming large droplet transmission of influenza in human outbreaks is indirect and limited.

Contact Transmission

Direct-contact transmission involves skin-to-skin contact and physical transfer of microorganisms to a susceptible host from an infected or colonized person, such as occurs when healthcare workers turn patients, bathe patients, or perform other patient-care activities that require physical contact. Direct-contact transmission also can occur between two patients (e.g., by hand contact), with one serving as the source of infectious microorganisms and the other as a susceptible host. Indirect-contact transmission involves contact of a susceptible host with a contaminated intermediate object, usually inanimate, in the patient's environment. Influenza can survive up to 48 hours on nonporous surfaces and up to 12 hours on porous surfaces, such as tissues and cloth. Viable virus can also be passed from tissues to hands for 15 minutes and from nonporous surfaces to hands for 24 hours. Virus can be recovered from hands for only five minutes if the hands are contaminated with a high viral titer. Contact transmission of influenza may occur through either direct skin-to-skin contact or through indirect contact with the virus in the environment and subsequent contact with mucous membranes (i.e., mouth, nose, or eyes).

[5] Uncertainty about the role of conjunctivae transmission results in uncertainty about recommending face and eye protection other than the standard precautions for protection against splash and spray.

Airborne Transmission

Airborne transmission occurs by dissemination and subsequent inhalation of airborne droplet nuclei or particles in the respirable to inspirable size ranges that contain the infectious agent. The term respirable refers to the size of the particles of less than 10 microns and can reach and deposit in the alveolar region of the lungs. Inspirable particles are in the range of 10 microns to 100 microns and do not reach the alveolar region, but can be inspired and accumulate in the thoracic and head airways of the respiratory tract. Microorganisms carried in smaller-size particles may be dispersed over long distances by air currents and may be inhaled by susceptible individuals who have not had close contact with (or been in the same room with) the infectious individual. Organisms transmitted in this manner must be capable of sustaining pathogenicity despite desiccation and environmental variation that generally limit survival in the airborne state. Preventing the spread of agents that are transmitted by the airborne route requires the use of special air handling and ventilation systems (e.g., negative-pressure rooms). The relative contribution of airborne transmission to influenza outbreaks is uncertain.

Whether influenza transmission can occur across long distances (e.g., through ventilation systems) or through prolonged residence in air is unknown. However, transmission may occur at shorter distances through inhalation of small-particle aerosols (droplet nuclei), particularly in shared air spaces with poor air circulation.

Some aerosol-generating procedures (e.g., endotracheal intubation, bronchoscopy) likely increase the potential for dissemination of droplet nuclei in the immediate vicinity of the patient. Therefore, healthcare workers who perform aerosol-generating procedures on influenza patients should use a higher level of respiratory protection (i.e., powered air purifying respirators.)

CDHS PANDEMIC RESPONSE ACTION STEPS

WHO Phase 1 and Phase 2

Interpandemic Period: No novel influenza subtypes have been detected in humans, but a novel subtype that has caused human infection may be present or circulating in animals.

- CDHS will provide influenza infection control recommendations, including respiratory protection measures, in consultation with the Centers for Disease Control and Prevention, the U.S. Occupational Health and Safety Administration (OSHA), Cal/OSHA, and other state and federal organizations.

- CDHS will promote seasonal influenza education of healthcare providers on the importance of respiratory etiquette and hand hygiene.

- CDHS Licensing and Certification Division and Division of Communicable Disease Control (DCDC), in consultation with the Occupational Health Branch will provide technical guidance to local health departments, hospitals, clinics, and home healthcare agencies on influenza infection control practices and procedures, healthcare worker surveillance, outbreak identification reporting and response, and other areas as needed.

- CDHS Licensing and Certification Division and DCDC will collaborate with local health departments, healthcare providers, and healthcare organizations to identify best practices of infection control for seasonal influenza. These best practices will be communicated to healthcare providers through multiple channels including the CDHS website at www.dhs.ca.gov and CAHAN.

- CDHS Licensing and Certification Division will monitor the compliance of healthcare facilities with state and federal infection control regulations and statutes.

Who Phase 3 and Phase 4

Pandemic Alert Period: Human infection with no or very limited human-to-human transmission.

- CDHS DCDC will recommend infection control guidelines for triaging patients entering the healthcare system (e.g., emergency departments, clinics, emergency medical services, physician offices), including spatial separation and masking (with a surgical mask) of potentially infected patients.

- CDHS Occupational Health Branch, in consultation with Cal/OSHA, will provide technical expertise and recommendations for protecting healthcare workers including recommendations for:

    - personal protective equipment for healthcare workers, including respiratory protection;

    - alternate care and out-patient settings;

    - situations in which personal protective equipment is in short supply or unavailable as a result of patient demand and census; and

    - "fitness-to-work" guidelines for healthcare workers. These guidelines will be based on the clinical symptoms of the influenza (fever of 38^0 C or 100.4^0 F, cough,

diarrhea), laboratory testing, probability of asymptomatic shedders, and risk assessment regarding exposure.

- CDHS DCDC, in consultation with the Occupational Health Branch, will provide technical consultation and recommendations for infection control practices and education of healthcare providers based on clinical, laboratory, surveillance, and epidemiologic data on the potential influenza pandemic, including:
    - instituting isolation and quarantine measures;
    - cohorting infected patients;
    - protecting non-influenza hospitalized patients; and
    - training and educating healthcare workers.

WHO Phase 5 and Phase 6

Pandemic Alert Period With Substantial Pandemic Risk: Larger clusters but still limited human-to-human transmission; sustained community transmission is possible and Phase 6, Pandemic Period: Increased and sustained transmission in the general population.

- CDHS DCDC will provide technical expertise and recommendations for:
    - alternate infection control measures and practices when personal protective equipment is in short supply or unavailable;
    - hospital infection control measures and equipment when cohorting large numbers of patients in alternate care facilities; and
    - postmortem care.
- CDHS Licensing and Certification Division will collaborate with local health departments to ensure effective infection control measures in alternate care sites and in isolating and cohorting influenza patients in areas of the facility.
- CDHS Occupational Health Branch, in consultation with Cal/OSHA, will provide technical expertise and recommendations for protecting healthcare workers including:
    - protecting healthcare workers in alternate care and outpatient settings;

- protecting healthcare workers when personal protective equipment is in short supply or unavailable; and

- "fitness-to-work" guidelines for healthcare workers. These guidelines will be based on the clinical symptoms of the influenza (fever of 38^0 C or 100.4^0 F, cough, diarrhea), laboratory testing, probability of asymptomatic shedders, and risk assessment regarding exposure.

- CDHS Division of Drinking Water and Environmental Management will make recommendations for managing large quantities of infectious waste (medical and non-medical); and will coordinate with CDHS DCDC to ensure that the waste capacity needs of affected facilities (hospitals, alternate care sites) are identified in a timely manner. Situations in which the amount of medical waste exceeds normal operating capacity will be addressed by the facility's medical waste management plan. CDHS Division of Drinking Water and Environmental Management will address exceptions to the medical waste management plan on a case-by-case basis.

- CDHS will manage, procure, and allocate scarce infection control supplies and personal protective equipment to healthcare providers.

WHO Postpandemic Period

- CDHS will continue to monitor and assess surveillance, laboratory, epidemiologic, and clinical data in the postpandemic period.

- CDHS will, to the extent possible, evaluate the efficacy of infection control measures and practices during the pandemic, capturing best practices and lessons learned.

Appendix C.

RECOMMENDATIONS FOR INFECTION CONTROL IN THE HEALTHCARE SETTING

Infection Control Principles for Preventing the Spread of Influenza

The following infection control principles apply in any setting where persons with pandemic influenza might seek healthcare services (e.g., hospitals, emergency departments, outpatient facilities, residential care facilities, homes.) Healthcare facilities should be prepared to implement engineering and administrative controls and use of personal protective equipment to prevent all possible modes of transmission, including airborne. Airborne level of preparedness includes the following recommendations for respiratory protection:

- Respiratory protection programs for employees designated to wear respirators;
- Medical clearance for respirator users;
- Selection of a suitable respirator model through respirator fit testing; and
- Training programs for employees in respirator use.

Respiratory Hygiene and Cough Etiquette

Respiratory hygiene and cough etiquette are important strategies to contain respiratory viruses and limit their spread. The elements of respiratory hygiene/cough etiquette include:

- Educating healthcare workers, patients, and visitors on the importance of containing respiratory secretions to prevent transmission of influenza; and
- Posting signs in languages appropriate to the population served with instructions to:

- immediately report symptoms of respiratory infection to the healthcare provider;
- use source control measures (e.g., covering the mouth and nose with a tissue when coughing and disposing used tissues appropriately; applying a surgical mask on the coughing person as tolerated);
- perform hand hygiene measures after contact with respiratory secretions; and
- in common waiting areas, maintain to the extent feasible spatial separation (ideally at least three feet) between uninfected persons and person with respiratory infections.

Hand Hygiene

Hand hygiene includes both hand washing with plain or antimicrobial soap and water or use of an alcohol-based product (hand sanitizers, including gels, rinses, foams, and hand wipes) that does not require water.

- In the absence of visible soiling of the hands, approved alcohol-based products for hand disinfection are preferred over soap and water for superior immediate antimicrobial activity, reduced drying of the skin, and convenience
- If hands are visibly soiled or contaminated with secretions, healthcare workers should wash their hands with soap (either non-antimicrobial or antimicrobial) and water.
- Healthcare workers should perform hand hygiene after removing gloves, before and after patient contacts, and after removing personal protective equipment.

Safe Work Practices

Healthcare workers must follow safe and consistent work practices and adhere to infection control policies and procedures**.**

- Facility infection control policies and procedures should include education for employees on safe work practices including “hand awareness” (i.e., being alert to touching and possible hand contamination).
- Healthcare workers should practice good hand hygiene at all times; avoid touching eyes, nose, mouth, or exposed skin with contaminated hands (gloved or ungloved); and remove contaminated gloves before touching surfaces (door knobs, light switches, keys, keyboards) and perform hand hygiene.

Personal Protective Equipment

Healthcare facility infection control policies and procedures should include measures to protect the healthcare worker from possible exposure and illness. Adherence to these measures is paramount to preventing transmission and infection and must be emphasized during provider education, monitoring, and follow up. Hospitals should consult Cal/OSHA requirements pertaining to personal protective equipment; these requirements may change as new standards addressing aerosol transmissible infectious diseases are promulgated.

Respiratory Protection

Current respiratory protection guidelines for influenza in healthcare facilities are for protection from droplet transmission; however, the role of small-particle airborne transmission of influenza remains undetermined. As long as there is uncertainty, the selection of respiratory protection for pandemic influenza must be assessed, using available evidence on the specific characteristics of the pandemic strain.

Because of the uncertainty about modes of transmission, CDHS recommends that in the early phases of the pandemic (WHO Phase 3, 4, and early Phase 5) with a single case or cluster(s) of cases, healthcare workers should use, at a minimum, an N-95 respirator when caring for a suspected or confirmed pandemic influenza patient. The current national recommendation for healthcare workers in an influenza pandemic is droplet precautions; however, CDHS recommends a higher level of protection until evidence of the transmission characteristics of the emerging pandemic strain demonstrates characteristics similar to seasonal influenza. At that time (WHO late Phase 5 and Phase 6), airborne precautions and N-95 respirators may not be needed for routine patient care, but should be reserved for high-risk care (i.e., aerosol generating procedures).

To ensure supply and appropriate use of limited supplies of N-95 respirators, hospital infection control policies should address the prioritization and allocation of respirators and specify target groups of workers that will wear N-95 respirators based on their role in direct patient care and exposure risk. Prioritization may include using respirators when in close proximity (three feet or less) of the patient, performing direct patient care, or transporting patients. N-95 respirators are disposable equipment and should not be reused.

Aerosol-generating procedures (e.g., bronchoscopy, intubation) create a higher concentration of pathogen-containing aerosol. Therefore, a higher level of respiratory protection than an N-95 respirator, such as powered air purifying respirators (PAPR) with N-100 (HEPA) filters should be used when the use of the PAPR does not interfere with the performance of the procedures. Aerosol-generating procedures should be conducted in an isolation room whenever possible.

Healthcare facilities must comply with all applicable OSHA and Cal/OSHA standards and guidelines. N-95 and other respirators should be used in accordance with a respiratory

protection program as specified by Cal/OSHA regulations, including medical evaluation, training, and fit testing. Facilities should anticipate and order adequate supplies and medically clear, fit-test, and train potential respirator users in advance.

CDHS DCDC, in consultation with the Occupational Health Branch and Cal/OSHA, will provide technical recommendations to healthcare providers for appropriate respiratory protection measures and equipment for the pandemic influenza based on clinical, laboratory, surveillance, and epidemiologic data. In collaboration with local health departments and healthcare providers, CDHS will educate healthcare workers and the public on appropriate respiratory protection measures.

Gloves

Gloves made of latex, nitrile, vinyl, or other synthetic materials are appropriate. However, if possible, latex-free gloves should be available for all healthcare workers to prevent the development of latex allergies. Healthcare workers should:

- Wear a single pair of gloves for contact with blood and body fluids and during any hand contact with respiratory secretions (e.g., providing oral care, handling soiled tissues);
- Ensure gloves fit comfortably;
- Remove and dispose of gloves after each patient use; do not wash gloves for reuse;
- Perform hand hygiene after removal of gloves;
- Use other barriers (e.g., disposable paper towels, paper napkins) when there is limited contact with a patient's respiratory secretions; and
- Emphasize hand hygiene and hand awareness in healthcare workers, patients, and visitors.

Hospital infection control policies should address the prioritization of gloves when they are in short supply. Prioritization could include reserving gloves for situations in which extensive patient or environmental contact with blood and body fluids is likely, such as during suctioning.

Gowns

- Most routine patient interactions do not require gowns.

- Healthcare workers should wear a gown if soiling of personal clothes or uniform with a patient's blood or body fluids, including respiratory secretions is anticipated, for example:
    - during procedures that may generate increased small-particle aerosols of respiratory secretions (e.g., endotracheal intubation and bronchoscopy);
    - during procedures or activities involving holding the patient close (e.g., restraining a child); and
    - during other patient care activities in which contact or exposure is likely (changing linens, ambulating a patient).
- Healthcare workers may use a disposable gown of synthetic fiber or cloth; the gown must fit the wearer and fully cover the area to be protected.
- Healthcare workers should wear the gown only one time and discard it into a laundry or waste receptacle.
- Healthcare workers should perform hand hygiene after removing the gown.
- Healthcare facility infection control policies must include proper donning and doffing procedures, including hand hygiene measures.
- Hospital infection control policy should address the prioritization of gowns when they are in short supply and designate alternate coverings (e.g., patient gowns). Infection control policies should clearly describe situations in which gowns are needed.

Eye Protection and Goggles

Droplet transmission and indirect contact transmission to the conjunctivae may be possible when a susceptible person is exposed to large-particle droplets generated from a person who has a clinical disease or is a carrier of the microorganism. If spray or splatter of infectious material is likely, goggles or a face shield should be worn, in addition to an N-95 respirator or surgical mask (e.g., within three feet of a coughing/sneezing influenza patient).

Disposal of Medical Waste

Standard precautions for contact with blood and body fluids (i.e., gloves) are required for biohazardous waste; gloves should be used when disposing of respiratory secretions. Support

personnel should be educated on proper personal protective equipment and procedures for handling waste materials.

Linen and Laundry

Healthcare facilities should use standard precautions for contact with blood and body fluids (i.e., gloves) for handling linen and laundry.

Dishes and Eating Utensils

Standard precautions for contact with blood and body fluids (i.e., gloves) are recommended for handling dishes and eating utensils used by a patient with known or possible pandemic influenza. Infection control policies and procedures must address proper cleaning and use. Disposable products are not required.

Patient Care Equipment

Healthcare facilities should follow standard practices for handling and reprocessing used patient care equipment including medical devices.

- Hospital personnel should wear gloves when handling contaminated patient care equipment.

- Hospital personnel should decontaminate patient care equipment with an EPA-approved hospital disinfectant before removing it from the patient's room and clean, disinfect, or sterilize re-usable patient care equipment as appropriate.

- Hospital personnel should decontaminate external surfaces of portable equipment used to perform x-rays and other procedures in the patient's room with an EPA-approved hospital disinfectant on removal of the equipment from the patient's room.

Environmental Cleaning and Disinfection

Cleaning and disinfecting environmental surfaces are important routine infection control measures in healthcare facilities. In addition to routine environmental decontamination,

healthcare workers should more frequently disinfect commonly touched surfaces in patient rooms and common areas and follow facility procedures for post-discharge disinfection of an isolation room.

Postmortem Care

Healthcare facilities should follow standard practices for the care of the deceased. These practices should include standard precautions for contact with blood and body fluids (i.e., gloves).

If autopsy or procedures are performed on a deceased person with suspected or confirmed influenza and the procedures generate higher concentration of aerosols (e.g., cutting through bone), a powered air purifying respirator (PAPR) with an N, P, or R-100 cartridge should be worn.

Laboratory Specimens and Practices

Healthcare workers should follow standard facility and laboratory practices for collecting, handling, transporting, and processing laboratory specimens.

Other Infection Control Measures

- Limit contact between infected and non-infected persons.
- Isolate infected persons (i.e., confine patients to a defined area as appropriate for the healthcare setting).
- Limit contact between patients who are ill with pandemic influenza and nonessential personnel and visitors.
- Promote spatial separation in common areas (i.e., sit or stand as far away as possible, at least three feet) to limit contact between symptomatic and non-symptomatic persons.

DETECTING PERSONS ENTERING THE FACILITY WHO MAY HAVE PANDEMIC INFLUENZA

Infection control policies and procedures should include detection measures to limit exposure to infected individuals. Hospitals should post visual alerts in appropriate languages at the entrances of the hospital (e.g., emergency departments, clinics, lobby areas) to:

- Instruct persons with respiratory symptoms to inform the first person of contact at the hospital of their symptoms when they enter the facility;
- Instruct persons with respiratory symptoms to practice respiratory hygiene and cough etiquette;
- Discourage unnecessary visits or limit visits to medical facilities; and
- Educate patients, families, and visitors about infection control measures at home and in the community.

Triage of Symptomatic Persons

During the peak of the pandemic, emergency departments and hospital-based clinics may be overwhelmed with patients seeking care. Facilities should consider implementing the following measures.

- **Patient Triage**
    - Establish a "triage officer" to manage patient flow, including deferring or re-directing patients who do not require emergency care.
    - Designate a separate waiting area for patients with influenza-like symptoms. Consider placing triage and waiting areas outside of the main facility e.g. adjacent clinics, conference rooms, etc. If this is not feasible, the waiting area(s) should allow spatial separation (three feet) from other patients.
- **Healthcare Worker Triage**
    - Implement a system to screen all healthcare workers for influenza-like symptoms before assuming duty.
    - Implement "fitness-for-work" criteria for employees to return to work.

Isolation Precautions and Patient Placement

Standard precautions should be used with all patients. For any novel influenza strain, the mode of transmission and recommendations for isolation precautions (i.e., droplet, contact, airborne) and patient placement must be determined at the time of the pandemic, based on the best available evidence at that time. All precautions discussed in this section are airborne

precautions, which CDHS recommends for addressing a novel influenza virus until it becomes clear that airborne precautions are not needed. Planning considerations include the following.

- Hospitals should develop policies and procedures to limit admission of influenza patients to those with severe complications who cannot be cared for outside the hospital.

- During aerosol-generating procedures (e.g., bronchoscopy, endotracheal intubation), hospitals should use a negative-pressure isolation or procedure rooms to decrease the risk of transmission within the hospital.

- Immunocompromised patients may shed virus for longer periods and should be placed on contact and airborne precautions for the duration of their illness.

In the early phases of the pandemic (WHO 3, 4, and early 5), with small clusters of patients, but limited human-to-human transmission, hospitals should consider the following:

- Placing patients with suspected or laboratory-confirmed illness caused by a novel pandemic influenza virus into rooms with engineering controls (i.e., negative-pressure isolation rooms) or cohort these patients to minimize the risk of influenza transmission;

- Placing patients with known or suspected pandemic influenza on contact and airborne precautions for up to 14 days from the onset of symptoms; and

- Admitting influenza patients to a single-patient room or to an area designated for cohorting patients with influenza.

Cohorting Patients

During a pandemic, other respiratory viruses may be circulating concurrently in the community. To prevent cross-contamination of respiratory viruses, hospitals should assign only patients with confirmed pandemic influenza to the same room. Hospitals should:

- Implement cohorting early in the course of an outbreak to accommodate an anticipated surge of patients;

- When determining areas to cohort patients, consult with facility engineers to address ventilation systems that are not shared with other areas or rooms;

- Ensure that personnel assigned to cohorted units do not “float” or otherwise work in other patient care areas; and

- Limit the personnel entering the cohorted areas to those necessary for patient care and support.

Patient Transportation

- Hospitals should limit patient movement and transport outside of isolation areas to medically necessary purposes.

- Hospitals should use portable equipment (e.g., portable x-ray equipment) in the isolation area(s) and clean the equipment after each use, according to facility and equipment manufacturer's guidelines.

- During transportation, patients should wear a surgical mask. If a patient cannot tolerate a surgical mask, apply the most practical measure to contain respiratory secretions such as placing a sheet or towel loosely over the nose and mouth or head.

Visitors

Hospitals should:

- Screen visitors for signs and symptoms of influenza before entry into the facility and exclude persons who are symptomatic;

- Limit visitors to persons who are necessary for the patient's emotional well being and care;

- Ensure patients wear a surgical mask, if tolerated, while visitors are in the room;

- Assume that family members accompanying the patient to the facility have been exposed to pandemic influenza and should wear surgical masks;

- Educate visitors to pandemic influenza patients on the importance of wearing surgical masks and using good hand hygiene and respiratory and cough etiquette; and

- Post instructions on respiratory and cough etiquette and hand hygiene and make necessary supplies available.

Chapter 6.

CASE MANAGEMENT

INTRODUCTION

Healthcare providers are essential to detect the initial cases of novel or pandemic influenza in a community. Early identification of cases through heightened clinical awareness of disease and swift action for isolation and treatment can benefit the individual patient and may slow the spread of influenza in the community. At any phase of a pandemic, rapid diagnosis and clinical care can avert severe complications.

While healthcare providers play an essential role in detecting the earliest cases of infection with a pandemic influenza virus, making the diagnosis may be complicated by the lack of specific clinical findings and commercially available laboratory tests that can distinguish a novel or pandemic virus strain from seasonal influenza. Clinicians, under the best of circumstances in the midst of a pandemic, will face significant challenges to: 1) quickly identify and triage cases, 2) conduct efficient and thorough evaluations, 3) initiate antiviral and other supportive therapies; and 5) anticipate clinical complications. Thus, mitigating the impact of an influenza pandemic consists of integrating sound clinical assessment, managing individual patients, and assessing locally available medical resources (e.g., rapid diagnostics, antiviral drugs and vaccines, healthcare personnel, and hospital beds.)

OBJECTIVES

The objectives of the California Department of Health Services' (CDHS) pandemic influenza activities for case management and treatment are to:

- Promote early identification, reporting, and proper management of cases to slow or contain the spread of disease in WHO Phase 3 and Phase 4;

- Provide education and guidance to local health departments in managing suspected and lab confirmed cases of novel virus strains as the pandemic evolves; and

- Communicate recommended practices, protocols and case management pertaining to avian and pandemic influenza to local health departments, healthcare providers and the public.

ASSUMPTIONS AND PLANNING PRINCIPLES

- The clinical characteristics of a novel or pandemic influenza virus and the groups at highest risk may differ from seasonal influenza A strains.

- Susceptibility to the pandemic influenza or novel influenza virus will be universal prior to vaccination.

- After the pandemic, the novel virus is likely to continue circulating and to contribute to seasonal influenza.

- People may be asymptomatic while infectious and the incubation period may be as little as two days, as with seasonal influenza.

    - Viral shedding will occur one-half to one day before the onset of illness.

    - Shedding will be the heaviest in the first two days after symptoms appear.

    - Children are typically heavy viral shedders in the first few days of illness (one day before onset of illness and two days after).

    - The infectious period in adults is typically three to five days, in some children and the immunocompromised viral shedding may persist for several weeks. These estimates will be revised based on viral shedding studies available on pandemic strain.

- Healthcare providers must be prepared to prioritize patient care, allocate scarce resources, and manage patient surge as well as consider using alternate care sites applying modified standards for patient care.

CDHS PANDEMIC RESPONSE ACTION STEPS

WHO Phase 1 and Phase 2

Interpandemic Period: No novel influenza subtypes have been detected in humans, but a novel subtype that has caused human infection may be present or circulating in animals.

- CDHS Division of Communicable Disease Control (DCDC), in collaboration with the CDHS Joint Advisory Committee on Public Health Preparedness, will develop, update,

and distribute California-specific guidelines for controlling interpandemic influenza in healthcare and other congregate settings at the start of the influenza season.

- Based on CDC guidance, and in coordination with local health departments, CDHS will develop and distribute protocols on case management and laboratory diagnostics. CDHS will work with local health departments to distribute protocols to settings where cases and their contacts might be diagnosed.

- CDHS will work with local health departments to ensure that clinicians and laboratory scientists know how to access the most current recommendations for novel or pandemic influenza case identification, reporting, management, and laboratory testing.

WHO Phase 3 and Phase 4

Pandemic Alert Period: Human infection with no or very limited human-to-human transmission.

- In coordination with CDC, CDHS will develop case management protocols to ensure that suspect human cases of novel or pandemic influenza virus infections are promptly identified, isolated, and source(s) of exposure (animal vs. human) determined. Case management protocols for clinicians will address:

    - screening criteria (clinical and epidemiologic, including travel and occupation);

    - notification of local health authorities;

    - case management (infection control precautions, laboratory testing, appropriate evaluation and treatment, nationally recommended management and treatment protocols); and

    - identification of potentially exposed contacts and assistance with management of contacts.

- CDHS will distribute to local health departments protocols on case management and laboratory diagnostics for avian and novel viruses as well as seasonal influenza virus.

- CDHS, in coordination with CDC, will develop and distribute guidance on managing patients who test negative for novel or pandemic influenza virus, addressing the potential for false negative findings, and clinical and epidemiologic criteria that warrant continued suspicion.

- CDHS, in coordination with CDC and local health departments, will revise and distribute virus transmission prevention and control guidelines to reflect the circumstances of Phase 3 and Phase 4.

- CDHS and local health departments will continue to educate clinicians and laboratory scientists on how to access the most up-to-date recommendations for novel or pandemic influenza case identification, reporting, management, and laboratory testing.

- CDHS, in coordination with CDC guidelines, will distribute to local health departments revised guidance on vaccination, prophylaxis, and treatment, based on the most current national and state recommendations, including a prioritized list of treatment and prophylaxis recipients and ensure the revised guidance is available to healthcare institutions and practitioners.

- CDHS, in collaboration with medical and professional societies will develop treatment protocols, standards and procedures for austere care, altered standards of care, and alternate care sites to direct patients to the most appropriate level of care in the community rather than acute care hospitals during an influenza pandemic.

- As isolated cases emerge, CDHS will manage the allocation and distribution of antiviral drugs in the CDHS stockpile to local health departments.

- CDHS will work with its Medical Care Services program (Medi-Cal); the Departments of Managed Health Care, Mental Health, Alcohol and Drug Programs, and Social Services; local health departments; and others to develop recommendations and guidelines for health plans, provider groups, and private practitioners.

WHO Phase 5

Pandemic Alert Period With Substantial Pandemic Risk: Larger clusters but still limited human-to-human transmission; sustained community transmission is possible

- CDHS, in coordination with CDC guidance and local health departments, will revise and distribute protocols and guidelines to reflect the circumstances of Phase 5.

- CDHS Emergency Pharmaceutical Services Unit will manage, allocate, and distribute vaccines, antiviral drugs, and other medications in the CDHS stockpile and the California distribution from the Strategic National Stockpile.

WHO Phase 6

Pandemic Period: Increased and sustained transmission in the general population

- CDHS will continue actions initiated in previous phases.

Appendix D.

CLINICAL GUIDELINES FOR PANDEMIC INFLUENZA

This appendix is intended to be a guide for clinicians for screening, assessing, and managing pandemic influenza patients and is based on guidance from the U.S. Department of Health and Human Services.[6]

ASSUMPTIONS

- During WHO Phases 1 through 5, early recognition of illness caused by a novel influenza A virus will rely on a combination of clinical and epidemiological features.
- During WHO Phase 6, diagnosis will be clinically oriented because of the likelihood that any severe febrile respiratory illness is caused by pandemic influenza.
- Management of influenza is based primarily on sound clinical judgment regarding the individual patient as well as an assessment of locally available resources (e.g., rapid diagnostics, antiviral drugs, hospital beds; see Chapter 4: Healthcare Planning).
- Early antiviral treatment shortens the duration of illness due to seasonal influenza and is expected to have similar effects on illness due to avian or pandemic influenza viruses (see Chapter 8: Pandemic Influenza Antiviral Drug Program).
- Clinical management must also address supportive care and management of influenza-related complications.

[6] U.S. Department of Health and Human Services Pandemic Influenza Plan, November 2005.

CLINICAL GUIDELINES FOR WHO PHASES 1 THROUGH 5

The following criteria are based on the features of recent avian influenza A (H5N1) cases but are intended for use in evaluating suspected cases of infection with any novel influenza A virus. During WHO Phases 3 through 5 human infections with novel influenza A viruses will be an uncommon cause of influenza-like illness; therefore, both clinical and epidemiologic criteria should be met.

Clinical Criteria

- Any suspected cases of infection with avian influenza virus must first meet the criteria for influenza-like illness, defined as:
    - temperature of > 100.4° F (38° C); **and**
    - either sore throat or cough or dyspnea.
- Clinical criteria may be modified as the characteristics of the pandemic evolve.

Epidemiologic Criteria

- Travel risks: persons have a travel risk if they have:
    - recently visited or lived in an area affected by highly pathogenic avian influenza A outbreaks in domestic poultry or where a human case of avian influenza has been confirmed; and either
    - had direct contact with poultry; or
    - had close contact with a person with confirmed or suspected avian influenza.
- Occupational risks:
    - persons who work on farms or live poultry markets;
    - persons who process or handle poultry infected with known or suspected avian influenza strains;
    - workers in laboratories that contain live animal or novel viruses; and
    - healthcare workers in direct contact with a suspected or confirmed avian influenza case.

Initial Management of Patients Meeting Criteria for Avian Influenza

When a patient meets both the clinical and epidemiologic criteria for a suspected case of novel influenza, healthcare personnel should initiate the following actions:

- Implement infection control precautions for avian influenza (see Chapter 5: Infection Control in the Healthcare Setting);
- Notify local and state health departments of the patient meeting the criteria as quickly as possible to facilitate initiation of public health and protective measures;
- Obtain clinical specimens for avian influenza A virus testing and arrange for transport to local or state public health laboratories (see Chapter 3: Laboratory Testing Capacity);
- Evaluate alternative diagnosis, based only upon laboratory tests with high positive predictive value (e.g., blood culture, viral culture, pleural fluid culture, etc.);
- Decide on inpatient or outpatient management based on clinical assessment, assessment of risk, and whether adequate precautions can be taken at home to prevent the potential spread of infection; see CDHS recommendations for lab confirmed, WHO Phase 3 H5N1 cases at: www.dhs.ca.gov/ps/dcdc/VRDL/html/FLU/H5N1;
- Initiate antiviral treatment; and
- Assist public health officials with identifying potentially exposed contacts.

CLINICAL GUIDELINES FOR WHO PHASE 6

During WHO Phase 6, the primary goal of rapid detection is to identify and triage cases of pandemic influenza. During this period, the healthcare system may be overwhelmed with suspected cases, restricting the time and laboratory resources available for evaluation. Evaluation will therefore focus predominantly on clinical and basic laboratory findings, with less emphasis on laboratory diagnostic testing and epidemiologic criteria.

Clinical Criteria

- Any suspected cases of infection with avian or novel pandemic influenza virus must first meet the criteria for influenza-like illness, defined as:
    - temperature of > 100.4° F (38° C); **and**

- either sore throat or cough or dyspnea.

- Clinical criteria may be modified as the characteristics of the pandemic evolve.

Epidemiologic Criteria

- During WHO Phase 6, an exposure history will be marginally useful for clinical management when disease is widespread in a community. There will be a relatively high likelihood that any case of influenza-like illness during that time will be pandemic influenza. Once pandemic influenza is widespread, clinical criteria will be sufficient for classifying the patient as a suspected pandemic influenza case.

Initial Management of Patients Meeting Criteria for Pandemic Influenza

Healthcare personnel should initiate the following activities:

- Follow local and state health department recommendations on reporting of patients who meet the criteria for pandemic influenza;

- If the patient is hospitalized, implement infection control precautions for pandemic influenza (see Chapter 5: Infection Control in the Healthcare Setting);

- Obtain clinical specimens for general evaluation, as clinically indicated and according to the recommendations from local and state health departments issued at the time of the pandemic;

- Decide on inpatient, outpatient, or alternate care site management. The decision to hospitalize will be based on the physician's clinical assessment of the patient and the availability of hospital beds and personnel. Acute care hospitals should be used to manage the most acute patients, and alternate care sites and home care used for less acute patients; and

- Review Chapter 7: Pandemic Influenza Vaccine Program and Chapter 8: Pandemic Influenza Antiviral Drug Program for information on target groups, allocation, and distribution.

CASE MANAGEMENT RESOURCES

- Clinical Case Management Procedures from CDC at: www.cdc.gov/flu/

- Listing of areas affected by Avian Influenza A (H5N1 and other current novel strains):
  OIE - www.oie.int/eng/en_index.htm
  WHO – www.who.int/en/
  CDC – www.cdc.gov/flu/
- Limiting Occupational Risk from the Occupational Health and Safety Administration at:
  www.osha.gov/dsg/guidance/avian-flu.html

- CDHS Pandemic Influenza Preparedness and Response Plan at www.dhs.ca.gov

- CDHS Division of Communicable Disease Control Pandemic Influenza Working Group recommendations and documents for local health departments for Phase 3 H5N1 cases in California including:
  CDHS Screening Form for Suspect Avian (H5N1) Influenza
  Suspect Avian Influenza Case Report Form
  Avian Influenza Infection Control Guidelines
  Guidelines for Specimen Collection
  Specimen Submittal Form for Suspect Avian Influenza
  H5N1 Biosafety Guidelines
  at: http://www.dhs.ca.gov/ps/dcdc/VRDL/html/FLU/H5N1/

Chapter 7.

PANDEMIC INFLUENZA VACCINE PROGRAM

INTRODUCTION

The United States has used influenza vaccines for more than 50 years as the primary method for preventing influenza and its complications. Annual influenza vaccine development requires input from international organizations, advisory committees, the U.S. Department of Health and Human Services, and licensed vaccine manufacturers. This multi-step process typically takes nearly a year of work.

The amount of vaccine that can be produced in time to be used in an influenza season is a function of the capacity of the industrial manufacturing base and the growth characteristics of the viruses used to produce the vaccine. Increased domestic vaccine manufacturing capacity would enhance the supply of vaccine using current production techniques, and allow for adequate supply during a pandemic. In addition, developing new production techniques would also enhance supply. The Federal Government is working closely with vaccine manufacturers to expand vaccine production capacity, and is actively supporting research and development of new vaccine technologies that will allow influenza vaccine to be made available more quickly in the event of a pandemic. Adequate planning and assessment of pandemic influenza vaccine procurement, allocation, and distribution is essential for an effective pandemic vaccine intervention.

OBJECTIVES

The objectives of the California Department of Health Services' (CDHS) Pandemic Influenza Vaccination Program are to:

- Allocate, distribute, and coordinate administration of pandemic influenza vaccine as rapidly, efficiently, and ethically as possible to target groups and populations; and

- Monitor the safety and effectiveness of pandemic influenza vaccination.

ASSUMPTIONS AND PLANNING PRINCIPLES

- With assistance from CDHS Emergency Pharmaceutical Services Unit, CDHS Immunization Branch will allocate and distribute vaccine to local health departments.

- Local health departments will develop plans and prepare to store, track, and administer vaccine.

- Vaccine delivery is less dependent on pandemic stage than on vaccine availability, CDC recommendations, and CDHS priorities.

- Three U.S. vaccine manufactures and others outside of the United States are conducting clinical trials of H5N1 vaccines. No manufacturers have completed clinical trials, and there is no federal policy for use of prepandemic vaccine.

- Two doses of vaccine administered at a minimum of four weeks apart will likely be required to develop maximal immunity to the novel virus. Further data on the safety and immunogenicity of a novel virus vaccine after one versus two doses will result from on ongoing human clinical trials.

- The federal government will purchase pandemic vaccine produced during the first few months (anticipated 3 to 6 million doses per week) and distribute it to states.

- State public health agencies will control the vaccine and be responsible for storage, security, allocation, distribution, and tracking. This vaccine supply will be used to vaccinate priority groups determined by CDC guidelines, the Division of Communicable Disease Control Pandemic Influenza Work Group, and the CDHS Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization Strategies.[7] (See Appendix D.)

- Adopting a consistent statewide pandemic influenza vaccination prioritization policy and practice for California will maximize the acceptance and effectiveness of the intervention. A single statewide prioritization policy will minimize confusion and increase the public's confidence in the pandemic response.

- The importance of consistent application of State of California vaccine priority groups must be weighed against local conditions. The local health officer may request a vaccine priority group variance from CDHS based upon emergent needs.

[7] A subgroup of the CDHS Joint Advisory Committee on Public Health Preparedness.

- Once vaccine is available, it will take several months to produce an adequate supply for the U. S. population. When first available, the federal government will distribute limited supplies of vaccine to states on a pro-rated basis. California comprises approximately 12 percent of the U.S. population, and can expect to receive 360,000 to 720,000 doses per week.

- New cell culture methods to increase vaccine production capacity are still early in development and are several years from approval.

- The vaccine may be administered and distributed under Investigational New Drug protocols, requiring informed consent before administration, follow up for second dose if required, and monitoring for possible adverse events. Alternatively, vaccine may be administered under U.S. Food and Drug Administration Emergency Use Authorization. Emergency Use Authorization procedures minimize the administrative burden and may be preferable to Investigational New Drug protocols to facilitate streamlined and efficient administration of vaccine.

- The necessary legal authority for implementing potentially extraordinary measures to distribute vaccine (e.g., allowing non-licensed volunteers to administer vaccine[8]) and secure distribution sites under emergency conditions should be planned before a pandemic occurs.

- Collaborate on vaccine distribution plans with federal agencies, local health departments, bordering states, and Mexico. Local health departments will be responsible for coordinating with providers and stakeholders and tribal entities within their jurisdictions.

Federal Role in Pandemic Influenza Vaccine Production, Allocation, and Distribution

The U.S. Department of Health and Human Services will:

- Work with the pharmaceutical industry toward the goal of developing, within 60 months, domestic vaccine production capacity sufficient to provide vaccine for the entire U.S. population (300 million courses) within six months after the recognition of a human influenza virus with pandemic potential and development of a vaccine reference strain;

[8] California law governs who may administer a vaccine. These people include physicians and surgeons (Health and Safety Code, section 1316.5), registered nurses (Business and Professions Code [BPC] section 2725 (b)(3)], physicians' assistants (BPC section 3502.1), pharmacists (BPC section 4052), and medical assistants under authorization and supervision of a licensed physician and surgeon or podiatrist (BPC section 2069). If the practitioner is operating under a particular practice guideline or protocol (e.g., a mass vaccination clinic), the licensed practitioner could delegate authority to screen or assess patients to a registered nurse, physician assistant, medical student, or resident. The suspension of legal provisions that limit who can perform medical procedures would require an order of the Governor during a declared state of emergency.

- Establish and maintain stockpiles of pre-pandemic vaccines adequate to immunize 20 million persons against influenza strains that present a pandemic threat and possibly become a virus with human pandemic potential;

- In collaboration with CDHS, local health departments, healthcare providers, and tribal entities, develop plans for the allocation, distribution, and administration of pre-pandemic vaccine;

- In coordination with Department of Homeland Security, and other agencies, and in collaboration with state and local governments, develop objectives for the use of, and strategy for allocating, vaccine and antiviral drug stockpiles during pre-pandemic and pandemic periods under varying conditions of countermeasure supply and pandemic severity; and

- In coordination with Department of Homeland Security and other agencies, present recommendations on target groups for vaccine when sustained and efficient human-to-human transmission of a potential pandemic influenza strain is documented anywhere in the world. These recommendations will reflect data from the pandemic and available supplies of medical countermeasures.

Monitoring and Evaluating Vaccine Coverage

- With support from CDHS, local health departments will have primary responsibility for monitoring and evaluating vaccine distribution and administration.

- CDHS will establish a database to track vaccine distribution and administration. This database will include information required for vaccine tracking (e.g., lot number, vaccination clinic dates, etc.). If an electronic system for vaccine tracking is not feasible for local health departments, a back-up paper system will be used. The paper system will document the same variables as the electronic system.

- Local health departments will have the primary responsibility for data entry. Local health departments will transfer data to CDHS Immunization Branch for analysis and interpretation.

Tracking Adverse Vaccine Reactions

- CDHS will use the Vaccine Adverse Event Reporting System, jointly coordinated by the FDA and CDC. Healthcare providers, patients, and vaccine manufacturers will report serious adverse events on paper forms, by telephone, or electronically.

- CDHS, in conjunction with local health departments, will analyze Vaccine Adverse Event Reporting System and other reports of serious adverse events to determine whether such events are reported more frequently than expected. CDHS will analyze signals of potential vaccine-associated events for biologic plausibility and may conduct epidemiologic studies to assess possible causation.

- CDHS may supplement the Vaccine Adverse Event Reporting System with additional surveillance and studies (e.g., active surveillance for adverse events in a sample of vaccines by telephone interviews or self-report diary cards).

Strategies for Using Limited Vaccine

- In the 1918 influenza pandemic, young, healthy adults were at high risk of morbidity and mortality. Currently, very young persons, elderly adults, and persons with underlying disease are at high risk of complications during interpandemic influenza outbreaks. Specific morbidity and mortality rates of any future pandemic remain unknown, and must be determined during the course of the pandemic.

- Vaccination strategies must be flexible and responsive to vaccine supply and the epidemiology of the pandemic. Epidemiologic investigations early in the pandemic will guide decision-making, by determining groups at highest risk for adverse health outcomes and age-specific case-fatality rates.

- CDHS will weigh programmatic feasibility when implementing priorities. For example, as vaccine supplies expand and after vaccination of the highest-priority target groups, it may be most feasible to vaccinate entire families or vaccinate by geographical area rather than further subdividing the population by priority.

- Vaccinating priority groups likely will be most efficient if the vaccination is given at the worksite (e.g., hospitals, fire stations, police stations). Prioritization strategies and implementation options for distribution of limited vaccine are included in Appendix D.

- CDHS will use risk communication strategies to explain the selection of priority groups (see Chapter 10: Pandemic Influenza Risk Communication Plan).

Pneumococcal Vaccine

Pneumococcal pneumonia is one of the most common secondary infections or complications of influenza.

- Increasing interpandemic pneumococcal vaccine coverage to those at highest risk of developing complications from influenza will be more feasible than implementing pneumococcal vaccination as an additional intervention measure once a pandemic begins.

- Improving pneumococcal vaccination coverage during the interpandemic period will decrease demand when a pandemic occurs and decrease the risk of a pneumococcal vaccine shortage.

- Consistent with current practice, private healthcare providers, home health agencies, visiting nurse associations, local health departments, and others will distribute and administer pneumococcal vaccine.

CDHS PANDEMIC RESPONSE ACTION STEPS

WHO Phase 1 and Phase 2

Interpandemic Period: No novel influenza subtypes have been detected in humans, but a novel subtype that has caused human infection may be present or circulating in animals.

No or limited supplies of pandemic vaccine are available. Some vaccine may be available in the private sector, the Strategic National Stockpile, or possibly a CDHS stockpile.

CDHS will:

- Promote seasonal influenza vaccination in traditional high-risk groups, particularly subgroups in which coverage levels are low (e.g., minorities and persons under age 65 years with chronic medical conditions). Increasing routine, annual vaccination coverage in these groups will facilitate access to these populations when a pandemic occurs. However, routine vaccination against the seasonal influenza virus is unlikely to protect against novel strains that emerge in a pandemic;

- Monitor seasonal vaccination in traditional high-risk groups through annual population-based surveys;

- Promote pneumococcal vaccination coverage to reduce the incidence and severity of secondary bacterial pneumonia in traditional high-risk groups;

- Promote seasonal influenza vaccination coverage rates among healthcare workers;

- Use the CDC Vaccine Information Statement, detailing the risks and benefits of the vaccine in English as part of its ongoing interpandemic influenza vaccine program, and will translate the Vaccine Information Statement into commonly used languages in California;

- Develop and distribute informational and promotional materials for interpandemic influenza vaccination to local health departments and healthcare providers (see Appendix F);

- Encourage local health departments to exercise their pandemic influenza vaccination plans;

- Develop, test, and implement a data management system (e.g., CDC Countermeasures Response Administration System) to allow state and local health departments to track influenza vaccine supply, distribution, and administration; and

- Communicate vaccine activities to Baja California.

WHO Phase 3 and Phase 4

Pandemic Alert Period: Human infection with no or very limited human-to-human transmission.

No or limited supplies of pandemic vaccine are available.

CDHS will:

- Communicate regularly with CDC, vaccine manufacturers, and distributors to obtain updates on plans for vaccine production and distribution;

- Convene regular meetings with the Pandemic Influenza Work Group and the Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization Strategies to determine prioritization strategies for vaccination when supplies are limited and to guide local health departments in distributing and prioritizing within their jurisdictions; the strategies will include:

    - CDC guidelines on priority groups critical to maintaining health, social, government, and emergency response services; specific target populations, including those at highest risk for complications from influenza; and

    - updating recommendations based on vaccine supply and global surveillance and epidemiologic data on characteristics of the novel virus;

- Prioritize groups for vaccination in severe vaccine shortages, moderate vaccine shortages, and no vaccine shortages;

- Develop protocols for vaccine delivery including:

- preparing delivery, storage, and distribution plans with local health departments;

- coordinating vaccine delivery, security, and receipt, including whether vaccine is delivered by Emergency Pharmaceutical Services Unit-arranged transportation, vendors via a centralized CDC distribution system, or manufacturers;

- determining whether to distribute vaccine to the public health sector (likely in the initial phase), the private sector, or a combination of the two;

- establishing and confirming storage sites for vaccine from Strategic National Stockpile vendors and manufacturers at existing secure vaccine storage depots;

- determining allocation of vaccine to local health departments based on population and priority group strategies;

- arranging secure delivery of vaccine from CDHS storage facilities to local health departments;

- providing local health departments with updated protocols for receiving, storing, securing, and administering vaccine, including encouraging identification of vaccination clinic sites; formation, review or updating of memoranda of understandings with those sites; and ensuring adequate security of vaccination clinic sites and storage facilities;

- coordinating with local health departments to assess the local availability of vaccination supplies (including syringes, gloves, bandages, gauze, first aid supplies, biohazard containers, emergency kits to manage anaphylaxis, etc.);

- encouraging local health departments to coordinate with the local Governor's Office of Emergency Services, Medical and Health Operational Area Coordinator, Regional Emergency Operations Center, Regional Disaster Medical Health Coordinator or Specialist, and the Joint Emergency Operations Center (JEOC) to assess local surge capacity to staff vaccination clinics, and to develop contingency plans for requests by local health departments for additional trained personnel;

- exercising the risk communication section of the CDHS Strategic National Stockpile Plan in conjunction with overall Emergency Pharmaceutical Services Unit planning; and

- exercising vaccine distribution plans annually;

- Review local health department plans for vaccinating population groups and provide support and guidance, and develop and distribute to local health departments vaccination

clinic guidance modified from CDC guidelines; the guidelines will include information on:

  - identifying vaccination clinic sites;
  - determining clinic staffing needs;
  - preparing duty statements for clinic staff;
  - developing protocols for vaccine storage, handling, and security;
  - supplying vaccination clinics;
  - developing clinic flow guidelines; and
  - sponsoring risk communications and public information;

- Recommend and test data management systems for tracking vaccine supply, distribution, security, and administration and resolve problems;
- Ensure that appropriate legal authorities are developed for implementing the proposed distribution plan, such as:
  - vaccination of target groups determined by state public health officials as essential for public health, safety and welfare;
  - allowing non-licensed volunteers to administer vaccine; and
  - ensuring liability coverage for non-licensed volunteers providing medical services or administering vaccine;
- Ensure that contingency plans have been considered for emergency distribution of unlicensed vaccine using Investigational New Drug or Emergency Use Authorization provisions, including implementing strict inventory control and record keeping, completing signed consent forms, and monitoring adverse events;
- Coordinate the development of materials for just-in-time training and refresher courses on vaccine delivery protocols and vaccine administration techniques for persons who do not normally administer vaccines;
- Continue to work with local health departments to encourage pneumococcal vaccination of persons aged 65 years and older and other persons recommended by the Advisory Committee on Immunization Practices to decrease morbidity and mortality associated with pandemic influenza;

- In collaboration with federal agencies, collaborate on vaccine distribution plans with local health departments, bordering states and Mexico; local health departments will be responsible for coordinating with providers and stakeholders and tribal entities within their jurisdictions; and

- Coordinate vaccine distribution plans with other state agencies (e.g., the California Departments of Corrections and Rehabilitation, Mental Health, and Developmental Services).

WHO Phase 5

Pandemic Alert Period With Substantial Pandemic Risk: Larger clusters but still limited human-to-human transmission; sustained community transmission is possible

Vaccine may still not be available or may be in limited supply. Preparations should be made to begin vaccinating target populations according to the pre-designated priority groups. (See Appendix E)

CDHS will:

- Communicate with local health departments, private physicians, stakeholders and the public to update the status of vaccine production, priority group designations, and guidelines for whom to vaccinate (see Chapter 10: Pandemic Influenza Risk Communication Plan);

- Review and refine plans prepared in Phase 3 and Phase 4 for delivering and storing vaccine as it becomes available, including:

    - evaluating additional mechanisms of vaccine delivery (e.g., Strategic National Stockpile, vendors via centralized CDC distribution system, or direct from manufacturers), receipt and transport of vaccine, and whether vaccine distribution is limited to the public health sector (likely in the initial phase), the private sector, or a combination of the two;

    - establishing other vaccine storage depots as available or needed, in addition to storage site(s) described in Phase 3 and Phase 4;

    - evaluating allocation of vaccine to local health departments, depending on population and priority group strategies;

    - coordinating secure delivery of prepandemic vaccine to local health departments, which are responsible for vaccine distribution within their jurisdictions;

- providing updated protocols to local health departments for receiving, storing, and administering vaccine, including identifying additional vaccination clinic sites as needed, forming memoranda of understanding with those sites, and ensuring adequate security of vaccination clinic sites and storage facilities;

- working with local health departments to assess the local availability of vaccine administration supplies as described in Phase 3 and Phase 4; and

- encouraging local health departments to coordinate with the county Office of Emergency Services, the Medical and Health Operational Area Coordinator, Regional Disaster Medical Health Coordinator or Specialist, and the JEOC to assess available local surge capacity for administering vaccination and for staffing vaccination clinics;

- If vaccine is administered under an Investigational New Drug protocol, ensure strict inventory control and record keeping, completion of signed consent forms, and monitoring of adverse events through a paper or electronic system;

- Ensure adequate staffing and communications for the Vaccine Adverse Event Reporting System, including:

  - designating a CDHS Vaccine Adverse Event Reporting System coordinator;

  - establishing a team to review and monitor for adverse events once vaccination begins;

  - coordinating and communicating with local health departments for adverse events reports and surveillance;

  - if needed, implementing and refining a database system for monitoring adverse events and reporting/interfacing with the Vaccine Adverse Event Reporting System;

  - alerting local health departments on the need to report adverse events to the Vaccine Adverse Event Reporting System; and

  - establishing a support hotline to assist new Vaccine Adverse Event Reporting System users and users encountering problems;

- Review guidelines for determining vaccination priority groups. Based on vaccine supply, surveillance data, and epidemiologic information, update the priorities as appropriate, in consultation with CDC, and the Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization Strategies (see Appendix D) including:

  - updating the estimate of high-risk and priority individuals needing vaccination; and

- coordinating the recommendations for vaccinating priority groups, updating estimates by jurisdiction, and distributing vaccines to local health departments;

- Coordinate the development and distribution of materials for just-in-time training and refresher courses to broadcast to local health departments (see Chapter 10: Pandemic Influenza Risk Communication Plan);

- Use epidemiologic studies of vaccine effectiveness to determine whether changes are needed to recommendations on vaccine formulation, dose, or schedule, in conjunction with CDC, when feasible; and

- In collaboration with federal agencies, collaborate on vaccine distribution plans with local health departments, bordering states and Mexico. Local health departments will be responsible for coordinating with providers and stakeholders and tribal entities within their jurisdictions.

WHO Phase 6

Pandemic Period: Increased and sustained transmission in the general population.

Vaccine may become more widely available during this phase. CDHS will begin facilitating procurement, coordination, and distribution of available vaccine.

CDHS will:

- Collaborate with local health departments, the Governor's Office of Emergency Services, Medical and Health Operational Area Coordinators, Regional Disaster Medical Health Coordinator or Specialist, and JEOC to assess available local surge capacity and communication needs to administer vaccination and staff vaccination clinics;

- Based on available supply, surveillance data, and epidemiologic information, review and update priority target groups to receive vaccine in consultation with CDC and the CDHS Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization Strategies (see Appendix D), including:

  - updating the estimate of high-risk and priority individuals needing vaccination; and

  - coordinating the recommendations for vaccinating priority groups, updating estimates by jurisdiction, and distributing vaccines to local health departments;

- Review surveillance data for changes in risk factors that could require modification of recommendations for priority groups receiving vaccine;

- Monitor Vaccine Adverse Event Reporting System data for evidence of adverse reactions and report the findings to CDC;

- Distribute vaccine to local health departments to allocate and vaccinate priority groups within their jurisdictions (including allocating to alternate care sites, as needed); close collaboration between public and private healthcare providers will be essential;

- Assist local health departments in modifying existing standing orders, signed by the local health officer or agency director, for vaccine administration including dosage, site of administration, contraindications to vaccination, precautions to vaccination, and response to anaphylaxis;

- In collaboration with federal agencies, collaborate on vaccine distribution plans with local health departments, bordering states and Mexico; local health departments will be responsible for coordinating with providers and stakeholders and tribal entities within their jurisdictions; and

- Through the JEOC's Public Information Officer and the Office of Public Affairs, provide frequent updates on vaccine availability and priority groups for stakeholders, partners, and the public (see Chapter 10: Pandemic Influenza Risk Communication Plan).

WHO Postpandemic Period

CDHS will:

- Provide a detailed retrospective characterization of the pandemic and evaluate the efficacy of pharmaceutical and non-pharmaceutical containment measures and emergency management strategies;

- In anticipation of a possible second pandemic wave, continue statewide surveillance and vaccination programs, with the goal of vaccinating all California residents; and

- Participate, in collaboration with CDC, in evaluating all aspects of the vaccination program, including vaccination coverage for first and second doses, priority groups and difficult-to-reach populations, monitoring of adverse events, and results of special studies to evaluate vaccine efficacy.

Appendix E.

PANDEMIC INFLUENZA VACCINE PRIORITIZATION PLAN

BACKGROUND

Vaccine is a key prevention strategy and control measure for decreasing the health consequences of a pandemic. Given the limited amount of vaccine that will be available early in a pandemic, CDHS must have an effective prioritization plan to determine target groups designated for initial vaccination.[9]

To address the need for a prioritization process, the Immunization Branch of CDHS formed the Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization.[10] CDHS contracted with the University of California, Berkeley Center for Infectious Disease Preparedness to work with CDHS and the advisory committee to develop a comprehensive vaccine prioritization plan.

No Comprehensive Prioritization Process Currently Exists

In November 2005, the U.S. Department of Health and Human Services (HHS) released broad-based national vaccination priority recommendations. HHS advises state and local health departments to create prioritization plans that provide specific definitions for priority groups, identify occupational categories and sub-categories within each broad priority designation, and select implementation strategies to deliver and dispense vaccine to the priority groups. A review of published prioritization plans reveals that they are limited in two key areas: 1) defining and incorporating the appropriate inputs into the prioritization process[11] and 2) articulating a well-developed methodology.[12]

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[9] See the CIDP Pandemic Influenza Project webpage for the project description, complete prioritization methodology, and all supplemental documents. (Weblink: www.idready.org/pandemic_influenza).

[10] A subgroup of the State Joint Advisory Committee comprising public health and medical care professionals, emergency planners, hospital administrators, physicians, academics, infectious disease experts, and a bioethicist.

[11] Prioritization inputs include intervention goals, vaccination strategies, vaccination criteria, and target groups.

[12] Refer to "Review of Vaccine Prioritization Plans" available at www.idready.org/pandemic_influenza for a complete discussion of the limitations of other jurisdictions' prioritization plans.

Objectives of the Prioritization Planning Process

CDHS has determined that a California prioritization plan should be:

- Systematic: based on a logical methodology to identify alternatives and project outcomes;
- Justifiable: based on epidemiologic, social science, and ethics literature and supported by best-practices research;
- Flexible: can be adjusted based on the changing epidemiologic characteristics of a pandemic;
- Adaptable: can be applied to different populations in different settings; and
- Transparent: clearly defined and incorporates expert opinion and feedback.

Choosing an Analytical Method

CDHS developed the Decision Analysis Scoring Tool that simultaneously analyzes multiple goals, criteria, and alternatives to develop an optimal prioritization scheme. The Scoring Tool is based on an Analytic Hierarchy Process, which is a "choice-based" modeling technique that helps decision-makers allocate resources across competing alternatives.[13] The Analytic Hierarchy Process evaluates target groups along competing vaccination criteria and assigns a numerical score to each group based on how well it matches the criteria. At the end of this process, the Scoring Tool produces a rank-ordered list of target groups prioritized for influenza vaccination that can be implemented within the state. These results will be evaluated on multiple implementation criteria to build an optimal vaccine implementation strategy.

[13] "Choice-based" modeling is a technique that forces decision makers to choose an option from a list of alternatives based on their opinions or preferences.

Assumptions

The Decision Analysis Scoring Tool is based on the following assumptions:

- In a pandemic, the availability of an effective vaccine will be limited.
- The primary goal of vaccination is to minimize health consequences (illness and death).
- Providing vaccine to persons before they become infected greatly decreases the likelihood of these persons developing serious complications (e.g. illness and death).
- Focusing interventions on reducing direct health consequences (illness and death) will also reduce indirect consequences (economic loss and social disruption).
- Groups determined to be of higher priority through the prioritization process will receive vaccinate first.

Decision Analysis Scoring Tool Methodology

The Decision Analysis Scoring Tool methodology comprises four stages:

- The Scoring Tool inputs (e.g. intervention goals, vaccination strategies, vaccination criteria, direct determinants, and target groups) are identified and defined in successive steps.
- The Scoring Tool survey is administered to determine the importance of the criteria and assess how well each target group meets the criteria. In addition, the scoring method is established. A target group's score is based on 1) the criteria weights; 2) the strength of match with a given criterion; and 3) the number of criteria met.
- The survey results are analyzed to develop the rank ordered priority list. The criterion scores for each target group are summed to produce the final prioritization score. These scores are arranged into a rank-ordered list of priority groups.
- The results are evaluated on multiple implementation criteria to develop an optimal vaccine implementation strategy.

Figure 7.1 illustrates how the Decision Analysis Scoring Tool methodology produces a rank-ordered priority list (stage 4 not shown).

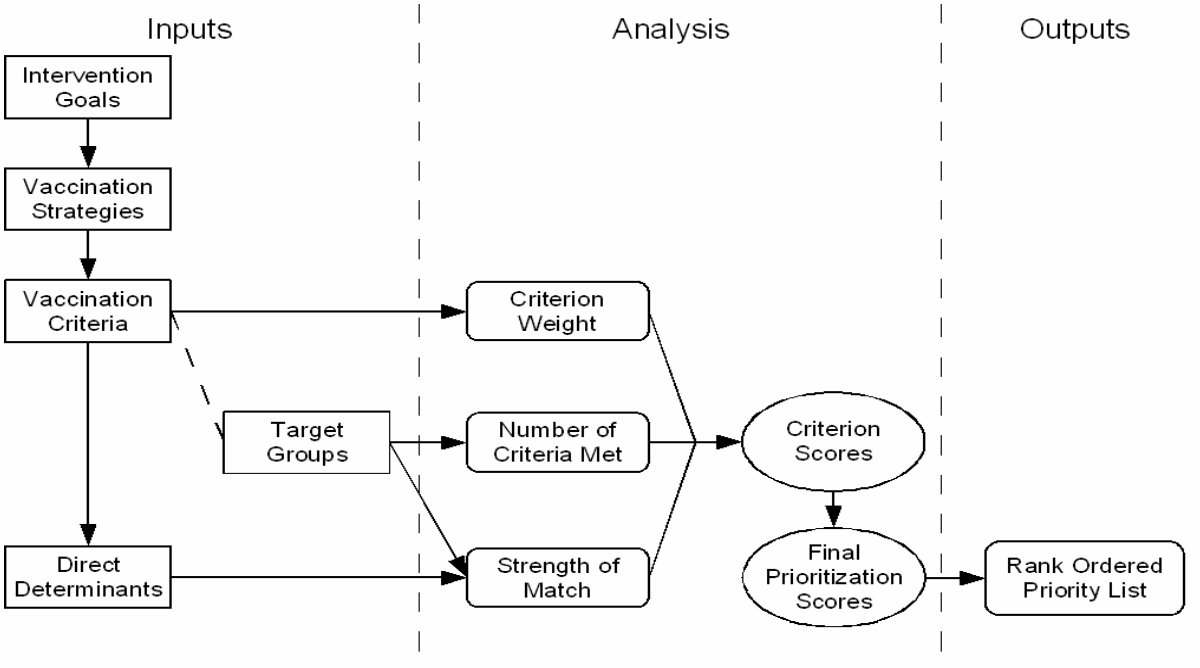

Figure 7.1 The Stages of Development of the Decision Analysis Scoring Tool
The methodology and rationale for each of these stages is discussed in detail in "Supplemental Document B "Decision Analysis Scoring Tool Methodology." (Weblink: www.dhs.ca.gov/ps/dcdc)

Vaccine Prioritization Inputs

INTERVENTION GOALS

CDHS identified three primary goals for prioritizing vaccine and determining the criteria an individual will need to qualify for prioritized vaccine:

- Minimize health consequences: reduce the number of severe illnesses and deaths caused by complications of pandemic influenza;
- Minimize social disruption: reduce disruption in essential community services and minimize social chaos and distress caused by pandemic influenza; and
- Minimize economic loss: reduce economic losses caused by reductions in production and consumption of goods and services because of pandemic influenza.

VACCINATION STRATEGIES

All possible approaches to allocating limited medical resources were identified, translated into vaccine rationing strategies, and evaluated to determine their appropriateness for use during a pandemic. Vaccination strategies had to achieve all three intervention goals. In addition, the strategies had to meet appropriate ethical, legal, political feasibility, and implementation standards.[14] Four rationing strategies meet these standards and are included in the prioritization methodology:

- Rationing to those who perform an essential emergency response role;
- Rationing by medical and prevention needs;
- Rationing by probability of successful immunization; and
- Rationing to those who perform an essential community role.

VACCINATION CRITERIA

To determine who would qualify for prioritization, vaccination criteria for each of the four vaccination strategies were developed. Emphasis was given to criteria that minimize health consequences. As a result, the Decision Analysis Scoring Tool methodology includes both epidemiologic as well as social role-oriented criteria.[15]

Relevant Strategy	**Criteria**
Medical and prevention needs	• Risk of transmission • Risk of infection • Risk of complication
Probability of successful immunization	• Vaccine effectiveness
Performs essential emergency response role	• Provides DIRECT emergency response service • Provides SUPPORT emergency response service
Performs essential community role	• Provides CRITICAL infrastructure service

DIRECT DETERMINANTS

Each criterion is further broken down into direct determinants that detail the characteristics that target groups must demonstrate to qualify for vaccination under that criterion.

[14] Refer to "An Analysis of Theoretical Approaches to Rationing" available at www.idready.org/pandemic_influenza for a complete discussion and evaluation of rationing strategies.
[15] Refer to "DAST Methodology" available at www.idready.org/pandemic_influenza for vaccination criteria definitions.

TARGET GROUPS

The target group list identifies populations that will likely meet one or more of the Decision Analysis Scoring Tool criteria and therefore should be targeted (or receive priority) for vaccine during the early stages of the pandemic.[16,17] The target groups were selected based on health-related characteristics and professional roles.

Target groups include persons with health-related characteristics that place them at high risk of developing influenza complications and persons who can transmit influenza to high-risk persons. These target groups are classified by their health status or health characteristic and in some cases by their age. Role-based target groups perform roles essential to the emergency response during a pandemic or maintain critical infrastructure. These groups are classified by the industry in which they work, the occupational setting where they work, and in some cases, the occupation or job title they hold.

The Prioritization Survey

The Decision Analysis Scoring Tool methodology is centered on a self-administered survey that assesses the relative importance of the prioritization criteria and evaluates the target groups along the criteria.[18]

The three main objectives of the survey are to:

- Determine the relative importance of the identified criteria in achieving the intervention goals;
- Determine how well each target group meets the relevant vaccination criteria; and
- Assess the strength and usability of a survey instrument to prioritize populations for influenza vaccine.

A pilot survey was distributed via email to the CDHS Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization. The results from the pilot survey were analyzed and prioritization scores were used to refine the survey.

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[16] Refer to "Target Population Group Profiles" available at www.idready.org/pandemic_influenza for detailed descriptions and population estimates of each of the target groups.

[17] The target group list was developed by the University of California, Berkeley, Center for Infectious Disease Preparedness researchers and vetted by representatives from the CDHS Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization as well as high-level staff within the CDHS Immunization Branch.

[18] Refer to "DAST Survey Questionnaire" available at www.idready.org/pandemic_influenza for the complete survey questionnaire.

CDHS will administer the survey to a representative statewide sample of pandemic preparedness experts beginning in June 2006. In addition to the medical care service and public health sectors, survey participants will include experts from commercial health, public administration, justice, and critical infrastructure industries. The results from this second round will be compared with priority recommendations in the HHS plan, as well as with other state pandemic plans. In addition, CDHS will recommend implementation strategies based on this priority list.

Vaccination Plan Supplemental Documents available on the website at www.idready.org/pandemic_influenza.

- **Review of Vaccine Prioritization Plans**. This document discusses the key limitations of currently published prioritization plans based on a literature review of international, national, and state vaccine prioritization plans.

- **Decision Analysis Scoring Tool Methodology**. This document presents an overview of the Decision Analysis Scoring Tool methodology broken down into each of the four stages. In addition, this document provides detailed definitions for the vaccination criteria and direct determinants.

- **An Analysis of Theoretical Approaches to Rationing**. This document presents a complete discussion of the theoretical approaches to rationing limited medical resources, a detailed description of how they were converted into relevant vaccine allocation strategies, and a full evaluation of the rationing strategies.

- **Target Population Group Profiles (Phase I)**. This document contains detailed profiles of the 69 target groups that likely meet one or more of the vaccination criteria. These target groups appear on the Decision Analysis Scoring Tool survey.

- **Decision Analysis Scoring Tool Survey Questionnaire (Phase I).** This document is the complete paper version of the Decision Analysis Scoring Tool survey that was administered to the CDHS Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization on June 21, 2005.

- **Decision Analysis Scoring Tool Survey Questionnaire (Phase II)**. This document is the complete paper version of the Decision Analysis Scoring Tool survey that was administered Statewide in June 2006.

- **Prioritization Score Calculation Method (Phase I)**. This document reviews how the results of the Decision Analysis Scoring Tool survey will be used to derive vaccine prioritization scores for target groups.

- **Decision Analysis Scoring Tool Survey Analysis (Phase I).** This document reviews the results from the Decision Analysis Scoring Tool survey in greater depth.

- **Sensitivity Analysis (Phase I)**. This document reviews in detail how population group prioritization scores vary when the criteria weights are simultaneously altered.

- **Implementation Strategy Analysis (to be completed)**. This document evaluates implementation options on relevant criteria to select an "optimal" implementation strategy for the State.

- **Discussion of Decision Analysis Scoring Tool Limitations**. This document describes the limitations of the Decision Analysis Scoring Tool methodology and presents recommendations on improvements that can be made to minimize these limitations.

Chapter 8.

PANDEMIC INFLUENZA

ANTIVIRAL DRUG PROGRAM

INTRODUCTION

Use of antiviral drugs is a key strategy in containing and responding to an influenza pandemic. Antiviral drugs have demonstrated effectiveness against infections caused by influenza A viruses in decreasing severity of clinical illness and the complications of illness such as lower respiratory tract infections (pneumonia) when used for treatment of ill persons within 24-48 hours of symptom onset. Antiviral drugs are also effective in preventing clinical illness with influenza A viruses when used for prophylaxis before or soon after exposure.

Creating federal and state stockpiles of antivirals is key strategy for pandemic preparedness. Even with large stockpiles, antiviral drugs are expected to be in short supply, requiring targeted use. Federal priority recommendations will reflect the federal pandemic response goals of limiting mortality and severe morbidity, maintaining critical infrastructure and societal function, diminishing economic impacts, and maintaining national security.

To preserve limited supplies, CDHS currently supports the federal recommendation to target antiviral drugs for 1) treatment of cases to decrease the impact on the healthcare system; and 2) post-exposure prophylaxis in select settings such as initial containment of cases during the early stages of a pandemic when isolated cases or limited clusters of cases can be identified and investigated, high-risk occupational exposures in healthcare settings, and exposure of high-risk person in institutional or household settings.

ANTIVIRAL DRUG CLASSES

Currently, there are two classes of antiviral drugs: adamantanes and neuraminidase inhibitors. Adamantine has demonstrated effectiveness against influenza A, whereas the neuraminidase inhibitors are effective for both influenza A and B. Both adamantanes and neuraminidase inhibitors are most effective against influenza when administered in the earliest stages of illness.

Adamantanes include amantadine and rimantadine. Both are available in proprietary and generic formulations, as capsules, tablets, or syrup, and they are inexpensive. Influenza virus can rapidly develop resistance to these drugs.

The neuraminidase inhibitors oseltamivir and zanamivir are each licensed for production by only a single manufacturer, and as of 2006, they are not available as generic formulations in the United States. Zanamivir is currently available only in an inhalational form, so is limited to treatment of children aged seven and older without any underlying airway disease like asthma. Oseltamivir is taken orally and can be used for either treatment or prophylaxis of illness in patients one year of age and older. Resistance to oseltamivir can occur, but emerges more slowly than with adamantanes.

Current federally approved recommendations, links to supporting clinical studies, and prescribing information for antiviral drugs used for treatment and prophylaxis during emergence of a novel or pandemic influenza can be found at:

http://www.pandemicflu.gov/vaccine/#drugs
http://www.cdc.gov/flu/whatsnew.htm#new
http://www.fda.gov/cder/drug/antivirals/influenza/default.htm
http://www.niaid.nih.gov/factsheets/fludrugs.htm

Current recommendations and research by the WHO regarding antiviral drugs for a novel or pandemic influenza strain are cited at:

http://www.who.int/csr/disease/avian_influenza/en/index.html
http://www.who.int/csr/disease/avian_influenza/guidelines/pharmamanagement/en/index.html

Given the current antiviral supply limitations, CDC, CDHS, and the California Medical Association do not recommended that individuals stockpile antiviral drugs in their homes nor that healthcare providers prescribe antiviral drugs to individuals with the indication of prophylaxis against pandemic influenza. These actions will further deplete the insufficient quantities of antiviral drugs available for treatment should an influenza pandemic begin and deprive individuals and patients with the highest priority for treatment and prophylaxis with these limited resources.

OBJECTIVES

The objectives of CDHS pandemic influenza activities for antiviral drugs are to:

- Establish a flexible strategy for the judicious and appropriate use of antiviral drugs from CDHS and Strategic National Stockpile stores in the event of a pandemic. The goal antiviral use is to contain spread of disease from initial cases of a novel influenza virus, decrease morbidity and mortality, and maintain essential services;

- Procure, allocate, distribute, and dispense antiviral drugs as rapidly, efficiently, and equitably as possible to target groups and populations during a pandemic; and

- Establish methods for monitoring the safety and investigating adverse events of antiviral drugs.

ASSUMPTIONS AND PLANNING PRINCIPLES

- The primary strategies for preventing pandemic influenza are the same as those for seasonal influenza, including early detection and treatment with antiviral drugs.

- When a pandemic begins, the supply of antiviral drugs will be limited.

- The federal government has established two primary goals for stockpiling existing antiviral drugs: 1) establishing and maintaining stockpiles adequate to treat 75 million persons (25 percent of the population), divided between federal and state stockpiles; and 2) establishing and maintaining a federal stockpile of 6 million treatment courses reserved for containment efforts.[19]

- When sustained and efficient human-to-human transmission of a potential pandemic influenza virus is documented anywhere in the world, the federal government will develop and distribute recommendations on target groups for antiviral drugs.[20]

- CDHS will procure and maintain a stockpile of antiviral drugs, up to the full federal allocation to cover 25 percent of California's population.

- CDHS antiviral drug stockpiles will be prioritized and allocated:

    - to treat lab confirmed cases, close contacts, high risk individuals and exposed healthcare workers in the early pandemic phases (WHO Phases 3, 4, and early 5); and

    - to treat cases with priority to health care professionals and public safety workers in late WHO Phase 5 and Phase 6.

- CDHS will update and revise antiviral drug prioritization and usage recommendations for California based upon federal recommendations once the pandemic is underway.

[19] Homeland Security Council, National Strategy for Pandemic Influenza Implementation Plan, May 2006, page 107.
[20] Ibid., Homeland Security Council, page 106.

- CDHS Emergency Pharmaceutical Services Unit will provide, according to the CDHS Strategic National Stockpile Plan, antiviral drugs from federal and state stockpiles to local health departments for allocation to target groups.

- Local health departments are responsible for antiviral drugs provided from federal and CDHS stockpiles including:

    - storing, securing, and handling drugs;

    - dispensing, tracking, and monitoring supplies;

    - documenting that antiviral drug recipients are in target groups according to CDHS recommendations; and

    - reporting summary data on dispensing practices to the CDHS Immunization Branch as required by CDC.

CDHS PANDEMIC RESPONSE ACTION STEPS

WHO Phase 1 and Phase 2

Interpandemic Period: No novel influenza subtypes have been detected in humans, but a novel subtype that has caused human infection may be present or circulating in animals.

- CDHS will establish and maintain a stockpile of antiviral drugs in coordination with existing Strategic National Stockpile supplies.

- CDHS will provide guidelines for the appropriate use and prescription of antiviral drugs during seasonal, non-pandemic influenza periods.

- CDHS Emergency Pharmaceutical Services Unit, in collaboration with the Immunization Branch, will inventory pharmaceutical vendors and distributors to estimate quantities normally available.

- CDHS will recommend strategies for distributing and dispensing antiviral drugs.

- CDHS and local health departments will collaborate with private-sector healthcare providers, health plans, healthcare organizations, pharmacies, and other stakeholders to educate providers and the public on the rationale for antiviral drug use strategies.

- CDHS will educate the public and healthcare providers on activities pertaining to antiviral drug stockpile development and use.

WHO Phase 3 and Phase 4

Pandemic Alert Period: Human infection with no or very limited human-to-human transmission

- CDHS Emergency Pharmaceutical Services Unit will communicate regularly with the CDC and antiviral drug manufacturers and distributors to obtain updates on plans for augmented antiviral drug stockpiles, production, and distribution.

- CDHS DCDC will convene a workgroup of healthcare partners to develop strategies for distributing and dispensing state and local stockpiles of antiviral drugs, and risk communications messages.

- CDHS will develop and distribute protocols for distributing antiviral drugs from the stockpile, including:

    - identifying database systems for monitoring antiviral supply, distribution and administration;

    - using the U.S. Food and Drug Administration's MedWatch system (www.fda.gov/medwatch) to monitor adverse events of antiviral drugs in a pandemic;

    - distributing and tracking antiviral drugs from CDHS and federal stockpiles if isolated cases emerge; and

    - recommending or developing a monitoring system and database to track drugs dispensed and distributed under Investigational New Drug or Emergency Use Authorization protocols, as determined by the U.S. Food and Drug Administration.

- CDHS VRDL, in collaboration with the CDC, will monitor for drug resistance of novel influenza virus and report trends and recommendations to the DCDC Pandemic Influenza Work Group.

- CDHS Emergency Pharmaceutical Services Unit will develop and test plans to receive, repackage, and distribute antiviral drugs from the Strategic National Stockpile.

- CDHS Emergency Preparedness Office, in collaboration with the Office of Public Affairs, will develop pre-event messages targeting healthcare providers and the public on antiviral uses, including indications, dosages, best practices, adverse events, and rationale for use.

WHO Phase 5

Pandemic Alert Period With Substantial Pandemic Risk: Larger clusters but still limited human-to-human transmission; sustained community transmission is possible

CDHS will:

- Communicate regularly with CDC, antiviral manufacturers, and distributors to obtain updates on antiviral drug supplies, production, and distribution;

- Communicate regularly with local health departments to review and revise antiviral administration and delivery plans and to provide updates on the status of antiviral supplies, production, antiviral use group designations and guidelines for use;

- Begin to pre-position antiviral drug in local health departments or regional centers;

- Communicate with healthcare partners, stakeholders, and the public to provide updates on the status of antiviral supplies, production, and antiviral use group designations and guidelines for use;

- Review recommendations and guidelines for antiviral use, considering antiviral supply, and epidemiologic and virology data;

- Distribute risk communication messages targeting healthcare providers and the public regarding antiviral use, including indications, dosages, best practices, adverse events, and the rationale for established priorities (see Chapter 10: Pandemic Influenza Risk Communication Plan); and

- Communicate updated antiviral drug use recommendations and guidelines to healthcare partners, stakeholders, and the public.

WHO Phase 6

Pandemic Period: Increased and sustained transmission in the general population

CDHS will:

- Continue all actions as indicated in previous pandemic phases;
- Receive antiviral drugs from the Strategic National Stockpile, activate and operate the State Receiving, Storing and Staging warehouse, and distribute antiviral drugs to local health departments or other designated receivers;
- Cooperate with CDC to design epidemiologic (e.g., case-control) studies to assess antiviral drug effectiveness and recommend changes in antiviral drug use strategies;
- On the basis of antiviral supply and surveillance and epidemiologic data, reprioritize antiviral drug use in consultation with CDC, the CDHS Joint Advisory Committee on Vaccine and Antiviral Prioritization Strategies, and the Division of Communicable Disease Control's Pandemic Influenza Work Group; CDHS will update estimates of high-risk and priority individuals by jurisdiction and communicate to local health departments;
- Monitor MedWatch data for evidence of adverse reactions to antiviral drugs, particularly drugs given under Investigational New Drug protocols, and based on the findings, collaborate with the CDC; and
- Continue to assess antiviral drug resistance trends reported by VRDL and CDC to recommend changes in antiviral drug use strategies.

WHO Postpandemic Period

CDHS will:

- Develop a detailed retrospective characterization of the pandemic to evaluate the efficacy of pharmaceutical containment measures and emergency management strategies;
- Replenish or restock the CDHS antiviral drug stockpile;
- Continue statewide surveillance and vaccination programs as vaccine supplies are widely available to vaccinate all California residents against the pandemic virus strain prior to subsequent pandemic waves; and

- Participate in evaluating the antiviral drug distribution and allocation activities during the pandemic, including use in target groups and special populations, adverse events, and conduct, in collaboration with CDC, studies to evaluate antiviral efficacy and associated resistance.

Chapter 9.

COMMUNITY DISEASE CONTROL AND PREVENTION

INTRODUCTION

This chapter addresses the containment of pandemic influenza in the community setting using non-pharmaceutical measures, such as isolation, quarantine, infection control, and community-based activity restrictions. Infection control measures used in healthcare settings are covered in Chapter 5. Chapters 7 and 8 address pharmaceutical control measures including vaccination and antiviral medications.

Non-pharmaceutical containment measures will be critical in the early phases of a pandemic when vaccine and antiviral drugs may be unavailable or ineffective and will be important adjuncts to pharmaceutical measures throughout the pandemic. Non-pharmaceutical containment measures reduce the risk of transmission by decreasing the probability of contact between infected and uninfected persons and by decreasing the probability that contact will result in infection. These measures can be applied at the individual or community level to persons who are ill and persons who are well. Individual measures may include isolating ill patients (those with symptoms), quarantining well persons who have had contact with ill persons, good hand and respiratory hygiene, and using personal protective equipment, such as masks and gloves. Community-based measures include community activity restrictions, such as restricting mass gatherings and closing schools, and limiting domestic and international travel. Appendix F and Tables 9.1 through 9.3 describe non-pharmaceutical containment measures in more detail.

The applicability of specific non-pharmaceutical containment measures will vary, depending on the characteristics of the novel influenza virus, the assessment of risk, resources, and public acceptance. Guided by surveillance, laboratory, epidemiologic and clinical data, the California Department of Health Services (CDHS) and local health departments will identify and implement the most appropriate measures at each phase of the pandemic to maximize impact on disease transmission and minimize impact on individual freedom of movement.

OBJECTIVES

The objectives of CDHS' pandemic influenza non-pharmaceutical containment measure recommendations are to:

- Prevent human cases caused by a novel virus before it is efficiently transmitted from human-to-human;

- Slow pandemic spread and gain time for strengthening preparedness measures, including augmenting vaccine and antiviral medication supplies when the virus is transmitted efficiently from person to person; and

- Reduce the morbidity and mortality associated with the pandemic.

ASSUMPTIONS AND PLANNING PRINCIPLES

- In the absence of adequate supplies of effective antivirals and vaccine, non-pharmaceutical containment measures are the primary means of mitigating the progression and impact of the pandemic.

- The effectiveness of most non-pharmaceutical containment measures is unknown and depends on characteristics of the evolving virus, including its pathogenicity (including infectious dose), principal mode of transmission (droplet or aerosol), onset and duration of viral shedding, attack rate (or infectivity) in different risk groups, the proportion of asymptomatic infections, clinical presentation, and compliance among the targeted populations. Because human influenza has a short incubation period, a short generation time (the average time between infection of the case and infection of the contacts), a high proportion of asymptomatic infections, and a non-specific clinical presentation, the utility of non-pharmaceutical containment measures may be limited.

- In addition to effectiveness, the selection of non-pharmaceutical containment measures will depend on feasibility (e.g., cost and availability of resources and supplies), potential for implementation within existing infrastructures, impact, and acceptance by the public.

- The clinical behavior of a novel influenza virus may be different from that of seasonal human influenza. The usual incubation period for human influenza averages two days with a range of one to four days. In the early pandemic alert periods when the circulating virus is more likely to be an avian rather than human strain, the incubation and infectious periods may be longer than seasonal human influenza. In the later pandemic phases, it is likely that the incubation and infectious periods of the novel virus will more closely resemble those of seasonal human influenza. These periods determine the potential

duration of various non-pharmaceutical containment measures. For the purposes of this chapter, the incubation period is defined as up to ten days; however, the time frame will be adjusted as more is known about the virus.

- Non-pharmaceutical containment measures must be adapted to the epidemiologic context of each pandemic phase, and recommendations regarding specific measures will change over the course of the pandemic. Once sustained human-to-human transmission is established, some non-pharmaceutical containment measures may have decreased effectiveness and will be dropped to conserve resources for addressing the main public health objective of reducing the number of cases and deaths.

- Measures with unknown effectiveness that the public chooses to adopt may be acceptable, as long as they do not divert resources and supplies, are not used as a substitute for other recommended control measures, are not discriminatory, and are reasonable.

- Communication is a critical aspect of all emergency planning and response. All programs involved in planning for and responding to pandemic influenza and all other public health emergencies must ensure timely and accurate communications. Communications procedures and protocols will be included in each phase of pandemic influenza planning and response to facilitate sharing of information and messages with CDHS divisions, other partners at the state and local level and the public (see Chapter 10: Pandemic Influenza Risk Communication Plan).

NON-PHARMACEUTICAL CONTAINMENT RECOMMENDATIONS: CDHS DECISION-MAKING

The appropriateness of non-pharmaceutical containment measures will vary, depending on the assessment of risk, resources, and public acceptance (Tables 9.1 and 9.2). Decisions about the use and timing of non-pharmaceutical containment measures should be supported by analysis of current clinical, laboratory, epidemiologic, and surveillance data.

In coordination with the Centers for Disease Control and Prevention (CDC), the Disaster Policy Council, and local health officers, CDHS Division of Communicable Disease Control (DCDC) Pandemic Influenza Work Group (PIWG) will regularly review available data and develop (to the extent feasible) evidence-based criteria for phase-specific recommendations. The PIWG will provide technical support and recommendations to the Director and CDHS executive staff on when to consider isolation, quarantine, and community-based activity restrictions.

If the Governor has not already proclaimed a state of emergency, CDHS will recommend one before implementing non-pharmaceutical measures with widespread public health and societal impact. Absent a Governor's proclamation of emergency, California Health and Safety Code

gives CDHS the legal authority to "require strict or modified isolation, or quarantine, for any case of contagious, infectious, or communicable disease, when this action is necessary for the protection of the public health…" (Health and Safety Code § 120145) or to "take measures as are necessary to ascertain the nature of the [contagious, infectious, or communicable disease] disease and prevent its spread" (Health and Safety Code § 120125). The Governor's Office of Emergency Services will coordinate implementation of activities and resources for measures that involve multiple agencies.

CDHS PANDEMIC RESPONSE ACTION STEPS

WHO Phase 1 and Phase 2

Interpandemic Period: No novel influenza subtypes have been detected in humans, but a novel subtype that has caused human infection may be present or circulating in animals.

- The DCDC PIWG, in conjunction with local health departments, will regularly assess available surveillance, laboratory, epidemiologic, and clinical data from the annual influenza season.

- CDHS DCDC will update and distribute guidelines for control of seasonal influenza in healthcare settings and other congregate settings. Guidelines will include relevant excerpts from federal guidelines on vaccination, prophylaxis, and treatment. CDHS Licensing and Certification Division, the Department of Social Services, the Department of Mental Health, and local health departments will distribute the guidelines to healthcare facilities and individual providers.

- CDHS DCDC and Office of Public Affairs will promote respiratory hygiene and hand washing to the public.

- CDHS DCDC and Office of Legal Services and local health officers will develop and distribute model protocols and best practices for isolation and quarantine for both individuals and communities. Protocols will address medical evaluation, enforcing orders, and non-compliant persons.

- CDHS, local health officers, and the Public Health Law Work Group will ensure that all needed state and local legal authorities exist to invoke isolation, quarantine, and community-based activity restrictions in a timely fashion.

- CDHS and local health departments will coordinate with partners and stakeholders who may be involved in enforcing isolation or quarantine orders in future pandemic phases.

- CDHS and local health departments will conduct drills and exercises on isolation and quarantine.

- The California Department of Food and Agriculture, the California Department of Fish and Game, the California Occupational Safety and Heath Administration (Cal/OSHA), and CDHS Division of Environmental and Occupational Disease Control Occupational Health Branch will develop recommendations for control of novel influenza virus in animals and animal settings, including safety measures for persons who may have contact with potentially infected animals during culling and other high-risk activities.

- Work with the California Department of Education and other partners in public and private sector to plan for potential use of community-wide interventions such as school closures.

WHO Phase 3 and Phase 4

Pandemic Alert Period: Human infection with no or very limited human-to-human transmission

- The DCDC PIWG, in conjunction with local health departments, will review clinical, laboratory, surveillance, and epidemiologic data and, in coordination with CDC and local health officers, will make technical recommendations about the potential use of non-pharmaceutical containment measures. The DCDC PIWG will make technical recommendations to the Director and CDHS executive staff on when isolation, quarantine, and community-based activity restrictions should be considered. CDHS will distribute recommendations to local health departments, as appropriate. Non-pharmaceutical containment measures that may be considered for use in community settings include:

    - **Isolation of persons with suspected novel influenza virus**: Depending on the characteristics and severity of illness, patients may be isolated at home or in the hospital. The duration of isolation will be based on the period of infectiousness associated with the specific novel influenza virus in question but may be longer than the usual incubation period for seasonal influenza.

    - **Managing close contacts**: Identifying and quarantining individuals or groups in contact with cases may be recommended. CDHS and local health departments will recommend contact tracing and management on a case-by-case basis, in consultation with CDC. Decisions will be based on the likelihood that the suspected case is infected with a novel influenza strain, the likelihood that the virus is or may become transmitted from person to person, and the feasibility of contact tracing. Quarantine may be lifted as soon as the exposed contact has remained without symptoms for a complete incubation period (if known) or up to ten days; other criteria may also be added (e.g., viral testing before release).

- **Managing small clusters of human infection with novel influenza virus**: Measures to contain small clusters of infection with novel influenza virus may include targeted antiviral prophylaxis and early detection of new cases. CDHS' Pandemic Influenza Work Group, in coordination with local health officers, will make recommendations on a case-by-case basis depending on the potential to cover the affected area and the ability to rapidly dispense antivirals. The use of antivirals is covered in Chapter 8.

- **Infection control:** Respiratory hygiene and hand washing will be promoted to the public.

- CDHS and local health departments will work with CDC quarantine stations and federal partners to evaluate and manage ill travelers arriving from affected regions who might be infected with a novel influenza virus. They will also provide information to travelers arriving in the United States from affected regions about the symptoms and risk factors associated with the novel influenza virus, self-monitoring and isolation should symptoms develop, and notifying public health officials in the event of illness.

- If animal sources are identified in California, CDHS Division of Environmental and Occupational Disease Control, Occupational Health Branch, working with the California Department of Food and Agriculture, the California Department of Fish and Game, and Cal/OSHA, will implement animal-worker exposure control measures.

- CDHS EPO, Office of Legal Services, Disaster Policy Council, and local health departments will invoke local and state legal authorities on isolation and quarantine, as needed, including the use of designated facilities to house cases and contacts that cannot or will not stay in their residences during isolation or quarantine.

- The Joint Emergency Operations Center, in collaboration with local health departments, Operational Areas, Regional Emergency Operations Centers, and the Governor's Office of Emergency Services, will monitor supplies to support isolation, quarantine, and other containment measures.

- Continue working with partners in public and private sector to plan for potential use of community-wide interventions.

- If recommended by CDHS or CDC, all agencies and organizations will continue other Phase 1 and Phase 2 activities.

WHO Phase 5

Pandemic Alert Period With Substantial Pandemic Risk: Larger clusters but still limited human-to-human transmission; sustained community transmission is possible

- The DCDC PIWG, in conjunction with local health departments, will review existing clinical, laboratory, surveillance, and epidemiologic data. The DCDC PIWG, in coordination with CDC and local health officers will provide revised recommendations to the Director and CDHS executive staff. CDHS will distribute revised recommendations to local health departments, as appropriate. In addition to those listed under Phases 3-4, recommendations may also include:

    - **Focused measures to increase social distance** (see Tables 9.1 and 9.2): CDHS and local health departments may recommend the use of focused measures, in consultation with CDC. Focused measures may be useful when transmission is limited and most cases can be traced to a known transmission setting.

    - **Broader community-based activity restrictions** (see Tables 9.1 and 9.2): Although the use of broader community-based measures in WHO Phase 5 is unlikely, CDHS and local health departments may consider and make recommendations for their use on a case-by-case basis, in consultation with the CDC.

    - **Infection control**: Respiratory hygiene and hand washing will be promoted to the public.

- CDHS EPO, Office of Legal Services, Disaster Policy Council, and local health departments will invoke local and state statutes on isolation, quarantine, and community-based activity restrictions, as needed.

- If recommended by CDHS or CDC, all agencies and organizations will continue other Phase 3 and 4 activities.

WHO Phase 6

Pandemic Period: Increased and sustained transmission in the general population.

Once efficient and sustained human-to-human transmission occurs, non-pharmaceutical containment measures are unlikely to halt further spread, and priorities shift to reducing morbidity and mortality. CDHS will recommend containment measures in the context of available vaccine and antiviral medications, public cooperation, resources, and the severity of illness. CDHS, in conjunction with local health departments, will regularly assess compliance with and effectiveness of non-pharmaceutical containment measures and will adjust recommendations as needed.

- The DCDC PIWG, in conjunction with local health departments, will review clinical, laboratory, surveillance, and epidemiologic data and update recommendations about non-pharmaceutical containment measures. The DCDC PIWG will also update recommendations to the Director and CDHS executive staff. CDHS will distribute revised recommendations to local health departments as appropriate. Recommendations may address:

    - **Activity restrictions for persons with fever**: Patient isolation and contact tracing and quarantine will likely cease, as these measures may no longer be feasible or useful. Persons with fever and respiratory symptoms and their contacts should be asked to stay at home and restrict their activities. The duration of the activity restrictions for persons with fever will be based on the infectious period associated with the specific novel influenza virus in question. During Phase 6, the period of infectiousness for the novel influenza virus will more likely resemble the usual incubation period for seasonal human influenza.

    - **Community-based activity restrictions**: CDHS and local health departments will implement community-based activity restrictions on an as-needed basis, in consultation with CDC. Although current data are lacking concerning effectiveness of these restrictions, measures such as closing schools, canceling large public gatherings, curtailing public transportation and other community activity restrictions may be recommended.

    - **Infection control**: Respiratory hygiene and hand washing will be promoted to the public. The benefit of wearing surgical masks by the public in community settings has not been established. This practice may not be mandated but may be permitted as long as it does not affect mask supplies needed for use in other settings, is not used in a discriminatory manner, and is not used as a substitute for other recommended disease containment measures.

- CDHS EPO, Office of Legal Services, Disaster Policy Council, and local health departments will invoke local and state legal authorities for isolation, and community-based activity restrictions including community-wide quarantine, as needed.

- If recommended by CDHS or CDC, all agencies and entities will continue other Phase 5 activities.

WHO Postpandemic Period

- CDHS will resume interpandemic measures after all waves of Phase 6 have ceased.

- CDHS will evaluate the efficacy of non-pharmaceutical containment measures during Phases 3 through 6.

Appendix F.

NON-PHARMACEUTICAL CONTAINMENT MEASURES: DEFINITIONS, EXAMPLES, AND CONSIDERATIONS

Non-pharmaceutical containment measures may limit the spread of disease in the general community and include isolation, quarantine, infection control, and community-based activity restrictions. **Isolation** separates or restricts movement or activities of ill persons with contagious disease to prevent transmission to others. **Quarantine** restricts movement and activities or separates well persons believed to have been exposed to infection, to prevent transmission to others. **Infection control** protects individuals from coming in direct contact with infectious materials or agents to limit transmission and include physical barriers (e.g., masks, gloves), hygiene (e.g., respiratory and hand hygiene), and disinfection measures. The principles of infection control are discussed Chapter 5. **Community-based activity restrictions** increase 'social distance' between members of a community by restricting or limiting public gatherings, public events, or group activities. To maximize their effectiveness, a combination of non-pharmaceutical measures tailored to the epidemiologic context of each pandemic phase will likely be recommended.

In California, both local and state health authorities can compel isolation and quarantine of individuals and communities when necessary to protect the public's health. These authorities are described in detail in Chapter 1 and in the Health Officer Practice Guide for Communicable Disease Control in California (Public Health Law Work Group) at:
http://www.dhs.ca.gov/ps/dcdc/dcdcindex.htm.

Table 9.1. Non-pharmaceutical Containment Measures: Definitions, Examples and Considerations – Adapted from U.S. Department of Health and Human Services Pandemic Influenza Plan, November 2005

Measure	Definition	Examples and Considerations
Isolation	The separation of infected persons from other persons for the period of communicability in such conditions as will prevent transmission of the agent. **Strict isolation** is confinement of the isolated individual to a room with a separate bed, with direct and room contact only with persons taking care of the individual caregivers. Appropriate disinfection and disposal of bodily excretions, secretion, garments, and objects in contact with the isolated individual must be assured. Persons caring for the isolated individual must take prescribed precautions to prevent the spread of infectious material from the individual's room (see 17 CCR §2516). **Modified isolation** is any other type of isolation, as prescribed and ordered by the local health officer and dependent on the disease involved (see 17 CCR §2517).	Ideally, during the pandemic (WHO Phase 6) persons who meet the criteria for a case of novel influenza and who do not require hospitalization should be isolated in their homes. During the earliest stages of a pandemic, when it is feasible, the home being considered should be evaluated by an appropriate authority to ensure that minimum standards (infrastructure, accommodations, resources for patient care and support) are met.
Quarantine	The limitation of freedom of movement of persons or animals that have been exposed to a communicable disease for a period of time equal to the longest usual incubation period of the disease, in such manner as to prevent effective contact with those not so exposed (see 17 CCR §2520).	Same considerations as above.
Individual-level containment measures	Measures applied to individuals, as opposed to groups or communities	Isolation of individual patients; quarantine of their close contacts.
Rapid identification and isolation of cases	The separation of suspected cases from others for a specific period (the infectious period).	

Table 9.1. Non-pharmaceutical Containment Measures: Definitions, Examples and Considerations – Adapted from U.S. Department of Health and Human Services Pandemic Influenza Plan, November 2005

Measure	Definition	Examples and Considerations
Quarantine of close contacts	The quarantine of individuals exposed to patients with communicable diseases; the contact remains separated from others for a specific period (up to 10 days after potential exposure) during which she or he is regularly assessed for signs and symptoms of disease.	May include family members, work or schoolmates, and healthcare workers. May be appropriate in situations in which the risk of exposure and subsequent development of disease is high and the risk of delayed recognition of symptoms is moderate. Persons in quarantine who experience fever, respiratory, or other early influenza symptoms require immediate evaluation by a healthcare provider.
Community-based activity restrictions	Measures applied to groups of people or communities.	Measures that may be beneficial and practical when there is a larger number of cases and more extensive viral transmission. In such settings, individual-level measures may no longer be effective or practical.
Focused measures to increase social distance and decrease social interactions	Measures applied to **specific** groups (as opposed to individuals or whole communities), designed to reduce interactions and thereby transmission risk within the group. Focused measures apply to groups or persons in specific settings, most but not necessarily, all of whom are at risk of exposure. Includes quarantine of groups of exposed persons and measures that apply to the use of specific sites or buildings.	Applicable in groups or settings where transmission is believed to have occurred, where the linkages between cases are unclear at the time of evaluation, and where restrictions placed only on persons known to be exposed are considered insufficient to prevent further transmission. Applied broadly, may reduce the requirement for urgent evaluation of large numbers of persons without explicit activity restriction (quarantine).
Quarantine of groups of exposed persons	A type of focused measure that quarantines persons who may have been exposed to the same source of illness; may be useful when there is limited transmission in an area and most cases can be traced to exposure to a known transmission setting (a specific school or workplace).	Includes persons exposed to a known case at a public gathering, on an airplane or other conveyance, at a school, workplace, apartment complex, and so on.
Restricting the use of specific sites or buildings or public events	A type of focused measure that may involve restricting entrance to a building or other site or requiring fever screening before entrance.	Cancellation of public events; closure of office buildings, schools, shopping malls, closure of public transportation such as subways or bus lines.

Table 9.1. Non-pharmaceutical Containment Measures: Definitions, Examples and Considerations – Adapted from U.S. Department of Health and Human Services Pandemic Influenza Plan, November 2005

Measure	Definition	Examples and Considerations
Community-wide measures to increase social distance	Measures applied to an entire community or region, designed to reduce personal interactions and thereby transmission risk. Includes measures applied to whole neighborhoods, towns, or cities.	Coordinated voluntary community and business closures, mandatory community-wide quarantine.
Coordinated community and business closures	Voluntary measures that coordinate simultaneous closure of offices, schools, transportation systems and other non-essential community activities, services and businesses for a specified period of time. All non-essential service personnel and community members are urged to stay at home.	Generally voluntary and can effectively reduce transmission without explicit activity restrictions (quarantine).
Community-wide quarantine (including cordon sanitaire)	Legally enforceable action that restricts movement into or out of the area of quarantine of a large group of people or community; designed to reduce the likelihood of transmission of influenza among persons in and to persons outside the affected area. Consists of closing community borders or the erection of a real or virtual barrier around a geographic area with prohibition of travel into or out of the area.	May be applicable to all members of a group in which extensive transmission is occurring, a substantial number of cases lack an epidemiologic link at the time of evaluation, and restrictions placed on persons known to be exposed are considered insufficient to prevent further spread. May be unnecessary, as less restrictive measures, such as coordinated community and business closures, may be equally effective.
Infection control measures	Use of physical barriers and hygiene measures to limit the risk of transmission.	Includes respiratory hygiene, cough etiquette, hand washing and hand hygiene, use of gloves, masks, and general hygiene and disinfection. Infection control is covered in more depth in Chapter 5.

CCR= California Code of Regulations

Table 9.2. Possible Community Containment Measures Based on Level of Novel Influenza Activity and Risk of Human Transmission - Adapted from U.S. Department of Health and Human Services Pandemic Influenza Plan, November 2005

Level of Influenza Activity	Response	Rationale
WHO Pandemic Phases 1 and –2; No novel influenza strains of public health concern in global circulation in humans	Preparedness planning	Use recommended response actions for interpandemic influenza prevention and control.
WHO Pandemic Phase 3; Circulation of a novel influenza virus subtype in animals and animal-to-human transmission resulting in isolated human infections or at most, rare instances of human to human transmission	Consider identifying and monitoring close contacts	Although individual containment measures may have limited impact in preventing the transmission of pandemic influenza (given the likely characteristics of a novel influenza virus), they may have great effectiveness with a less efficiently transmitted virus and may slow disease spread and buy time for vaccine development.
WHO Pandemic Phases 4; Limited novel influenza virus transmission abroad; all local cases (e.g., in California or the United States) are either imported or have clear epidemiologic links to other cases	Identify close contacts, consider quarantining close contacts	Same as above.
WHO Pandemic Phase 5; Limited novel influenza virus transmission in the area (e.g., within California or the United States), with either a small number of cases without clear epidemiologic links to other cases or with increased occurrence of influenza among their close contacts	Identify and quarantine close contacts if contact tracing is still recommended	Same as above.

Table 9.2. Possible Community Containment Measures Based on Level of Novel Influenza Activity and Risk of Human Transmission - Adapted from U.S. Department of Health and Human Services Pandemic Influenza Plan, November 2005

Level of Influenza Activity	Response	Rationale
WHO Pandemic Phase 6; Sustained novel influenza virus transmission in California, with a large number of cases without clear epidemiologic links to other cases; **control measures aimed at individuals and groups appear effective**	Focused measures to increase social distance; consider community-wide activity restrictions	Selective use of group quarantine (focused measures) early in a pandemic when the scope of the outbreak is focal and limited may slow the geographic spread and buy time for vaccine development.
WHO Pandemic Phase 6; Sustained novel influenza activity in California, with a large number of cases in persons without an identifiable epidemiologic link at the time of initial evaluation**; individual control measures are believed to be ineffective**	Consider community-wide measures such as coordinated community and business closures, and community-wide quarantine	When disease transmission is occurring in communities around the United States, individual quarantine is much less likely to have an impact and likely would not be feasible to implement Rather, community-based activity restrictions and emphasizing what individuals can do to reduce their risk of infection may be more effective disease control tools.
WHO Pandemic Phase 6 (between waves or pandemic subsiding); Decreases in the number of new cases, unlinked (or "unexpected") cases, and generations of transmission	Consider quarantining contacts	
WHO Postpandemic Period; Transmission has been controlled or eliminated, no new cases	Active monitoring in high-risk populations; continue for 2 to 3 incubation periods after control or elimination of transmission	

Table 9.3. Threshold Determinants for use in Decisions about Community Containment Measures - Adapted from U.S. Department of Health and Human Services Pandemic Influenza Plan, November 2005

Variable	Data Element
Case and contacts	Number of cases (absolute or estimated) Rate of incident cases Number of hospitalized cases Morbidity (including disease severity) and mortality Number and percentage of cases with no identified epidemiologic link Number of cases occurring among contacts Number of contacts under surveillance or quarantine
Healthcare resources	Hospital or facility bed capacity Staff resources Patient: staff ratio Number of ill or absent staff members Availability of specifically trained specialists and ancillary staff members Availability of ventilators Availability of other respiratory equipment Availability of personal protective equipment and other measures Availability of therapeutic medications (influenza and non-influenza specific)
Public health resources	Investigator to case and contact ratios Number of contacts under active surveillance Number of contacts under quarantine Ability to rapidly trace contacts (number of untraced or interviewed contacts) Ability to implement and monitor quarantine (staff member to contact ratio) Ability to provide essential services (food, water, and so on.)
Community cooperation, mobility, and compliance	Degree of compliance with voluntary individual isolation Degree of compliance with active surveillance and voluntary individual quarantine Degree of movement out of the community Degree of compliance with community-containment measures

Chapter 10.

PANDEMIC INFLUENZA

RISK COMMUNICATION PLAN

INTRODUCTION

Risk communication is a critical component of pandemic influenza preparedness. Effective communication guides the public, the news media, response agencies, healthcare providers, and other groups in responding to outbreaks, adhering to public health measures, and understanding state and local response efforts.

Risk communication during an influenza pandemic must be approached differently than during other disasters and emergencies. Pandemic influenza will be a widespread and long-term event that will strain national, state, regional, and local resources and that requires a plan for ensuring sustained societal functions. Special emphasis needs to be placed on communication with state and local partners to ensure the public receives consistent and current information on the status of the pandemic, the state's efforts, and the responsibility of individuals and families.

OBJECTIVES

The objectives of the California Department of Health Services' (CDHS) pandemic influenza risk communication plan are to:

- Prepare Californians for a pandemic;
- Educate the public on steps they can take to decrease the spread of illness through personal and local preparedness;
- Prepare pre-event messages and materials on pandemic influenza for public dissemination;
- Share messages with healthcare providers to enhance patient awareness regarding personal protective measures;

- Coordinate risk communication activities across state, regional, and local levels; and

- Collaborate with partners at the federal, state, and local level on messages, materials, and strategies.

RISK COMMUNICATION CONCEPTS

Communications with the public, partners, and providers during an influenza pandemic will follow the risk communication concepts listed below[21]:

- Provide the public with information about what is known and unknown and provide guidance for decision making to protect individual and family health;

- Coordinate and maintain consistency of messages to avoid confusion and build credibility and trust;

- Express empathy for victims;

- Provide information that is scientifically and technically correct and can be understood by all facets of the public, including non-English speakers;

- Minimize speculation, over-interpretation of data, and overly confident assessments and projections;

- Provide immediate and on-going information in response to intense and sustained demand; and

- Disseminate timely, accurate, and science-based information about pandemic influenza and the progress of the response.

RISK COMMUNICATION ASSUMPTIONS AND CHALLENGES

- **Public Communication**: A pandemic will be an international event. The public will turn to multiple sources for information, potentially resulting in conflicting or confusing messages. To reach California's diverse populations, CDHS will:

[21] U.S. Department of Health and Human Services Pandemic Influenza Plan, November 2005, Supplement 10: Public Health Communications.

- use multiple communication channels, such as websites, a hotline, and mass media, to disseminate messages and promote other information resources;

- communicate desired behavior to help the public follow public health guidance;

- produce materials in numerous languages and adapt materials for the hearing- and vision-impaired; and

- share information, materials, and strategies with state and local partners.

- **Public Education/Non-Pharmaceutical Community Containment**: The primary focus of a public education campaign will be self-protective actions and non-pharmaceutical community containment measures to slow the spread of the virus. Communications must help the public understand and comply with personal hygiene measures and community wide interventions such as business and school closures. Information will need to be shared broadly with public and private organizations affected by social distancing interventions that may result in marked economic impact.

- **Travel**: International travel can quickly spread the influenza virus globally. California is at particular risk with its many ports, international airports, and tourist destinations. Communications concerning travel precautions or restrictions should be accurate, prevent discrimination, and be widely shared.

- **Vaccine and Antiviral Shortages**: Communications must explain vaccine and antiviral shortages, identify and explain the necessity for target groups, and provide resources for information.

- **Overwhelming Healthcare Demands**: A pandemic will place demands on healthcare over a sustained period. Communications should include messages that help protect and maintain proper healthcare practices, identify appropriate use of medical services, provide information regarding alternate care sites, direct self-monitoring and reporting of symptoms, and address coping strategies and mental health needs.

- **Public Opinion**: Communications should increase public awareness of pandemic influenza, promote self-protection measures, explain state and local preparedness efforts, and build public confidence in preparedness efforts and CDHS' ability to respond.

OPERATIONAL STRUCTURE

This CDHS Pandemic Influenza Risk Communication Plan is consistent with the CDHS Public Health Emergency Response Plan and Procedures and the Strategic National Stockpile Risk Communication Plan. This plan is also consistent with the strategic approach and actions

identified in the 2005 CDHS Crisis and Emergency Risk Communication Tool Kit distributed to local health departments.

Communication is a critical aspect of all emergency planning and response. Programs involved in planning for and responding to pandemic influenza must ensure timely and accurate communication. CDHS will include communication procedures and protocols, in each phase of pandemic influenza planning and response, to facilitate information sharing with state and local level partners, and the public. CDHS' communication vehicles with local health departments include conference calls, e-mail, and posting information on the California Health Alert Network (CAHAN). CDHS will use similar mechanisms to share information with other state partners and the education and business sectors.

To ensure implementation of communication protocols and procedures during Joint Emergency Operations Center activation, CDHS will assume the following roles:

- **Office of Public Affairs**: In collaboration with the Joint Emergency Operations Center Public Information Officer, the Office of Public Affairs will maintain its role as CDHS lead in providing public information and responding to media inquiries.

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- **Joint Emergency Operations Center's Public Information Officer:** Lead responsibility for providing public information through the Emergency Preparedness Office's (EPO) website, CAHAN, fact sheets, sample materials, templates, and other related materials. The Public Information Officer coordinates with members of the CDHS Crisis Communications Team, including:

    - CDHS Office of Public Affairs;

    - Strategic National Stockpile Public Information Liaison;

    - Governor's Office of Emergency Services Joint Information Center; and

    - Local health department public information officers and risk communication leads.

- **CDHS' Program Public Information Liaisons**: CDHS programs may designate a liaison to assist with public information activities related to their program and coordinate with the Joint Emergency Operations Center's Public Information Officer. Activities may include coordinating with content specialists, recommending public information guidance, responding to rumors, arranging for spokespersons, and facilitating approval of new material.

- **Governor's Office of Emergency Services Joint Information Center**: In an emergency, the Joint Information Center is the central point for state information on the incident. The CDHS risk communication team will continue to provide information and consult with the Governor's Office of Emergency Service's Public Information Officer, and other key partners, on public information planning related to pandemic influenza

through regular meetings and briefings to include other key partners. The Joint Emergency Operations Center will communicate with the Joint Information Center, provide staff, and participate in message development. CDHS will provide materials such as fact sheets and templates to the Joint Information Center.

- **Other State Public Information Officers**: CDHS will share information with state partners, including the Office of Homeland Security; the Departments of Education, Fish and Game, Food and Agriculture, Mental Health, and Social Services; the Business, Transportation, and Housing Agency; the Emergency Medical Services Authority and others to ensure consistency and accuracy of information.

TARGET AUDIENCES, COMMUNICATION PARTNERS, AND STAKEHOLDERS

Collaboration during an event requires partner and stakeholder relationships to be established in advance. Developing common messages, sharing advanced planning strategies, understanding anticipated communication protocols, and identifying how organizational structures operate during a crisis will ensure a more collaborative effort during a pandemic.

CDHS will enhance its outreach activities to partners and stakeholders. A partial list of target audiences, partners, and stakeholders appears in Appendix F. CDHS will revise the list as needed.

CDHS PANDEMIC RESPONSE ACTION STEPS

WHO Phases 1 through 4

Interpandemic Period: No novel influenza subtypes have been detected in humans, but a novel subtype that has caused human infection may be present or circulating in animals.

Pandemic Alert Period: Human infection with no or very limited human-to-human transmission.

During the interpandemic and pandemic alert periods, communication strategies will focus on self-protective behaviors and non-pharmaceutical community containment actions, their purpose, and implementation.

CDHS will:

- Establish and maintain regular communications, through conference calls, e-mail list server updates, briefings, and CAHAN alerts, with state partners, local health departments, and others to coordinate consistent and accurate messages;

- Develop a comprehensive, multi-ethnic, multi-language public information campaign, working with partners and stakeholders (see Appendix F);

- Develop materials for educating the public and partners using U.S. Department of Health and Human Services (HHS) and CDC materials, California-specific information, and other materials;

- Display and model desired behaviors through written stories, radio spots, and other strategies;

- Develop television and radio public service announcements and materials for other public venues (billboards, posters, bus-boards, etc.), to educate the public on self-protective actions and pharmaceutical and non-pharmaceutical community containment efforts;

- Develop and translate into multiple languages communication resources and materials, including easy-to-read versions, such as:

    - static “cling-ons,” posters, and fliers on self-protective measures using graphics and easy to understand instructions;

  - informational materials on coordinated community and business closures;
  - tool kit with preparedness instruction for businesses (in collaboration with HHS, CDC and partners);
  - tool kit with preparedness instructions for schools (in collaboration with HHS, CDC, and the California Department of Education); and
  - response action sheets specific to pandemic influenza for inclusion in CDHS' Crisis and Emergency Risk Communication Tool Kit for local health departments;
- Develop and share presentations to educate selected audiences on pandemic influenza preparedness;
- Develop and distribute briefing packets for policy makers and share packet template with local health departments;
- Post website information for the public, healthcare providers, response partners, and the media;
- Adapt materials and information developed by HHS, CDC, WHO, and others, including culturally sensitive materials in multiple languages for dissemination via media, hotline, website, list servers, local health departments, and others;
- Design educational materials for groups likely to be disproportionately affected by the pandemic and work with appropriate agencies on development and distribution;
- Develop infrastructure and surge capacity for the CDHS emergency information hotline to provide recorded messages and live operators with advice nurse guidance;
- Provide training on communications to state and local health department staff;
- In coordination with state partners, determine CDHS' communications response to the first Californian diagnosed with the pandemic strain of influenza, the first case of H5N1 in poultry, and other key events;
- Reinforce emergency response training for communication staff, including training on the SEMS and the NIMS; and
- Promote public awareness of the priority groups for influenza vaccination and the rationale for selecting those groups.

WHO Phases 5 and 6

Pandemic Alert Period With Substantial Pandemic Risk: Larger clusters but still limited human-to-human transmission; sustained community transmission is possible

Pandemic Period: Increased and sustained transmission in the general population.

During the pandemic period, communication strategies will focus on continuation of self-protective measures, social distancing, enforcement of non-pharmaceutical community containment measures, such as school and work closures, and communication with partners and stakeholders.

During the response to an influenza pandemic, CDHS will fully activate risk communication efforts regarding non-pharmaceutical community containment measures. The Joint Emergency Operations Center will coordinate information related to California's response to the influenza pandemic and will coordinate health-related public information.

CDHS will:

- Inform CDHS risk communication response partners, and local health department risk communication or public information leads of the Joint Emergency Operations Center activation and pandemic influenza risk communication actions, including the public information campaign;

- Issue media notifications and share them with partners via e-mail and CAHAN;

- Communicate regularly with HHS, CDC, California Health and Human Services Agency, California Department of Food and Agriculture, the Governor's Office of Emergency Services, local health departments, and others on developing new materials, strategies, and communication priorities;

- Schedule regular briefings with partners, including local health department risk communication or public information leads;

- Provide CDHS spokespersons with updated key messages;

- In collaboration with local health departments, activate all components of the Risk Communication Plan;

- Promote self-protection measures such as respiratory hygiene and hand-washing;

- Provide public messages that promote positive coping skills and behaviors to reduce stress;

- Provide public awareness of non-pharmaceutical containment measures, such as coordinated community and business closures and "stay at home" messages;

- Reinforce social distancing messages, such as avoiding crowded areas and events;

- Model desired behavior with messages, information and support for non-pharmaceutical community containment and self-protection measures;

- Post information on CAHAN and the CDHS website with links to other credible sources;

- Use the CDHS emergency information hotline to provide recorded messages on self-protection and non-pharmaceutical community containment and live operator assistance regarding when to stay home or seek medical care;

- Schedule regular briefings with the press and share press releases with response partners via e-mail and CAHAN;

- Activate CDHS' Strategic National Stockpile risk communication plan when antivirals or vaccine are available and request that affected local health departments do the same;

- Use CDHS Public Information Officer surge capacity staffing for continued operation and to support public information efforts of local health departments; and

- Provide staff support for the continued operation of the Governor's Office of Emergency Services Joint Information Center;

WHO Postpandemic Period

The recovery and postpandemic period will address recovery efforts, including psychosocial needs and community return to normality. During this phase, CDHS will respond to additional waves of pandemic influenza and other outbreaks.

CDHS will:

- Continue all pandemic phase actions as needed to address additional waves of disease;

- Continue collaboration with mental health partners and others to provide recovery-focused messages to the public; and

- Support community recovery efforts by repeating and promoting self-protection messages as community norms.

Appendix G.

RISK COMMUNICATION RESOURCES, TOOLS, AND MATERIALS

Risk Communication Target Audiences

CDHS will target the following audiences for risk communication messages and information:

- the public;
- media, including ethnic media;
- local health departments;
- legislators, state, and local government officials;
- CDHS staff;
- healthcare community (healthcare providers and facilities, hospitals, clinics, doctors, nurses, etc.);
- business and community leaders;
- ethnic communities;
- first responders;
- agricultural workers;
- tourists and those taking mass transit;
- disabled;
- homebound;

- low-literacy;
- homeless;
- schools and children; and
- seniors.

Risk Communication Partners

CDHS will coordinate with local and statewide response partners to ensure message coordination, timely and accurate information dissemination and rumor control response, including:

- CDC and HHS;
- California Health and Human Services Agency;
- CDHS Divisions and Offices;
- Governor's Office of Emergency Services;
- Governor's Office of Homeland Security;
- California Department of Food and Agriculture;
- Emergency Medical Services Authority;
- Other state departments and agencies including:
    - Business, Transportation, and Housing Agency;
    - State and Consumer Services Agency;
    - Department of Aging;
    - Department of Corrections and Rehabilitation;
    - Department of Education;
    - Department of Industrial Relations;

    - Department of Mental Health;
    - Department of Rehabilitation;
    - Department of Social Services;
    - National Guard; and
    - Office of the Attorney General.
- California Legislature;
- Local health and mental health departments;
- Local transportation agencies;
- County Health Executives Association of California;
- California Conference of Local Health Officers;
- Tribal entities;
- Medical associations and societies;
- Hospitals and clinics;
- Emergency responders (fire/rescue; and law enforcement); and
- Red Cross and other community-based organizations.

Risk Communication Stakeholders

CDHS will ensure that the following key stakeholders remain informed regarding the pandemic response progress:

- Local elected leaders and administrators;
- Civic organizations and unions;
- Business and community leaders;

- Community-based organizations;
- Agencies serving special populations;
- School districts, Parent Teacher Associations, and colleges and universities;
- Mortuaries and funeral homes;
- Health insurance organizations; and
- Healthcare providers.

Communications Team

CDHS will maintain a team of trained risk communication specialists who will function in the capacities identified.

Public Information and Risk Communication Co-Leads:

- CDHS Deputy Director of Public Affairs, and
- CDHS Emergency Preparedness Office Risk Communications Lead.

Full activation in response to a pandemic may involve communication team and supplemental CDHS staff fulfilling the following roles:

- Media content and rumor control coordinator;
- Local health department coordination and support;
- CDHS emergency information hotline liaison and staff;
- Direct public outreach and partner/stakeholder coordinator;
- Multi-cultural and special populations outreach coordinator;
- Healthcare provider outreach coordinator; and
- Web masters.

Risk Communication Tools, Materials, and Tasks

Material Resources

CDHS will develop and provide media support materials for local health departments and other response partners that may include the following:

- Fact sheets;
- Frequently asked questions;
- Talking points;
- Questions and answers;
- Sample press releases for the first human case and first death; the human health implications of the first California bird testing positive for H5N1, coordinated community and business and school closures, protective measures, etc.;
- Posters, "cling-ons," signs, stickers, and so on, for distribution to local health departments, hospitals, clinics, restaurants, transportation portals (airports, train stations, ports, bus stations), gas stations, retail outlets, and other public gathering places;
- Websites and postings (CDHS, Governor's Office of Emergency Services, partner and stakeholder sites search engine pick-up, bulletin boards, list servers, links);
- Hotline (activation procedures, script, surge capacity, translation, staffing);
- Newsletters;
- Materials in multiple languages and low-literacy text;
- Material testing;
- Key messages; and
- Radio scripts, billboards, bus boards, poster text and radio public service announcements.

Media Outreach

CDHS will provide media response activities that may include the following:

- Guidelines and instructions for media relations;

- Press conferences;
- Press releases;
- Daily briefings;
- Media web postings;
- Video and audio clips;
- Video conferencing;
- Radio actualities;
- Radio and TV Public Service Announcements;
- Electronic press kits;
- Message monitoring;
- Ethnic media outreach; and
- Media monitoring and contact logs.

Public Education

CDHS will conduct community outreach and public education activities that may include the following:

- Website materials, including materials for key audiences such as providers;
- Toll-free phone lines, such as the CDHS Emergency Information Hotline;
- Presentations targeted toward community-based organizations;
- Message dissemination;
- Town halls, community presentations, etc.;
- Translation services;
- Partner outreach and briefings; and

- Outreach to stakeholders and special populations.

Information and Communications Team Management

CDHS will ensure that information is timely, accurate and staff is appropriately trained by ensuring the following practices:

- Examine current issues and messages daily;
- Evaluate effectiveness of strategies and messages, update or revise as needed;
- Discuss feedback from information loops;
- Determine message of the day and disseminate to team;
- Train spokespersons and update as needed (subject matter experts, bi-lingual, training);
- Build communication staff surge capacity (recruitment and training);
- Ensure that key staff is knowledgeable about the NIMS and SEMS and the emergency response process;
- Update team on status of planning and response; and
- Participate in tabletop drills, exercises, and briefings.

Websites/Fact Sheets

The links listed below were active as of June 2006:

- Government
  www.pandemicflu.gov

- Pandemic Influenza Fact Sheet
  http://www.cdc.gov/flu/avian/gen-info/pandemics.htm

- Avian Influenza Fact Sheet
  http://www.cdc.gov/flu/avian/gen-info/facts.htm

- Guidance to Travelers
  http://www.cdc.gov/travel/other/avian_flu_ah5n1_031605.htm

- Interim Guidance for U.S. Citizens Living Abroad
  http://www.cdc.gov/travel/other/avian_flu_ig_americans_abroad_032405.htm

- Sample CDC News Conference Transcript
  http://www.cdc.gov/od/oc/media/transcripts/t040127.htm

- Managing Anxiety in Times of Crisis
  http://mentalhealth.samhsa.gov/cmhs/managinganxiety/default.asp

- California Department of Health Services
  www.dhs.ca.gov

Additional Resources

- **CDC:** Presents information on the symptoms, treatment, and complications of the disease, prevention and control, the types of influenza viruses, questions and answers on symptoms, vaccination, and myths.
  http://www.cdc.gov/flu/avian/.

- **National Vaccine Program Office:** Presents an historical overview of pandemics that occurred throughout the past century (Spanish Flu, Asian Flu, Hong Kong Flu), and three influenza scares (Swine Flu, Russian Flu, and Avian Flu).
  www.dhhs.gov/nvpo/pandemics

- **World Health Organization:** Defines an influenza pandemic, explains how a new influenza virus can cause a pandemic, presents the consequences of an influenza

pandemic, explains the global surveillance systems, and provides links to other pandemic plans from other nations.
www.who.int/csr/disease/influenza/pandemic/en

- **The Public Health Preparedness and Response Capacity Inventory:** Resource for state and local health departments undertaking comprehensive assessments of their preparedness to respond to bioterrorism, outbreaks of infectious disease, or other public health threats and emergencies.
www.dhs.ca.gov/epo/PDF/NPSsmpxv1.pdf

- **CDC Cooperative Agreements on Public Health Preparedness:** State and local public health preparedness for and response to bioterrorism, other outbreaks of infectious diseases, and other public health threats and emergencies.
www.bt.cdc.gov/planning/continuationguidance

- **Epidemic Information Exchange:** Web-based communications network for information exchange among the CDC, state, and local health departments, and other public health professionals.
www.cdc.gov/mmwr/epix/epix.html

- **Centers for Public Health Preparedness:** A national system for competency-based training tools for the public health workforce.
www.asph.org/acphp

- **Strategic National Stockpile:** Information on the availability and rapid deployment of life-saving pharmaceuticals, antidotes, other medical supplies, and equipment necessary to counter the effects of nerve agents, biological pathogens, and chemical agents.
www.bt.cdc.gov/stockpile

- **Association of State and Territorial Health Officials**
www.astho.org

- **National Association of County and City Health Officials**
www.naccho.org

- **Infectious Disease Society of America**
www.idsociety.org

- **National Foundation for Infectious Diseases**
www.nfid.org

- **Institute of Medicine (IOM)**
www.iom.edu

- **World Health Organization (WHO)**
  www.who.org

Chapter 11.

BEHAVIORAL HEALTH AND PSYCHOSOCIAL CONSEQUENCES

Chapter in Development